Management and women's experiences of pregnancies lasting more than 41 gestational weeks

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To Johan, Simon, Gustav, and Maria

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ABSTRACT

It is well known that the risks for complications of both the foetus and the mother increase in post-term pregnancy. To date, there is no uniform worldwide guideline for when to induce a pregnant woman who has passed her estimated due date. Little research has been conducted about women's own experiences of a pregnancy ≥41 gestational weeks. The overall aim for the thesis was: 1) to investigate if a policy of induction of labour at 41 gestational weeks is superior, in terms of neonatal and maternal outcomes, versus induction at 42+0 gestational weeks, among healthy women with a low risk pregnancy. 2) To get a deeper knowledge about women's experiences of pregnancy ≥41 gestational weeks. Study I comprised the study protocol, and Study II the register based randomised controlled multicentre trial SWEPIS. In Study III the qualitative method phenomenology was used and the lifeworld hermeneutic approach in Study IV. The results showed no perinatal mortality in the early induction group compared to six perinatal deaths in the expectant management group, and no difference in primary outcome between the two groups. The results from the qualitative studies showed that the women experienced a state of limbo, a void, characterised by contradiction in relation to time, giving birth, and treatment from the caregivers. Further, the women experienced the time of waiting for the onset of labour as the start of a voyage into unknown waters. In conclusion, it is advantageous to induce at 41 gestational weeks, compared to induction at 42 gestational weeks, without increasing the risk for caesarean section or instrumental vaginal delivery. In addition, women need clear information and support to be strengthened in the transition from being pregnant to giving birth.

Keywords: experiences, hermeneutic, induction, late-term pregnancy, lifeworld, midwifery, perinatal mortality, phenomenology, postterm pregnancy, prenatal care, transition.

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SAMMANFATTNING PÅ SVENSKA

Det är välkänt att riskerna för komplikationer för både fostret och den gravida kvinnan ökar vid en överburen graviditet. Fostret har en ökad risk för asfyxi, kramper, mekoniumaspiration, lunginflammation, navelsträngskomplikationer, sepsis, skulderdystoci och perifera nervskador. För kvinnan ökar risken för disproportion, långdragen förlossning, post partum blödning, post partum infektion, akut kejsarsnitt och större vaginala bristningar.
I nuläget saknas det internationella riktlinjer för när gravida kvinnor som har passerat beräknat förlossningsdatum ska förlösas. Tidpunkten för igångsättning av förlossning skiljer sig åt både mellan länder och inom respektive land. Forskningsstudier som beskriver kvinnornas upplevelser av att ha passerat 41 graviditetsveckor saknas.
Det övergripande syftet med avhandlingen var tvådelat: 1) Att undersöka om igångsättning av förlossning i graviditetsvecka 41 (tidig igångsättning) är bättre för modern och barnets hälsa jämfört med igångsättning av förlossning i graviditetsvecka 42 (avvaktande handläggning/sen igångsättning) för friska kvinnor med en normal graviditet. 2) Att få en djupare förståelse av kvinnors upplevelser av en graviditet som varat $\geq$ 41 graviditetsveckor.
Studie I utgörs av studieprotokollet för den registerbaserade kontrollerade randomiserade multicenterstudien SWEPIS (SWEdish Post-term Induction Study). Studie II är genomförandet av SWEPIS där kvinnorna lottades till tidig eller sen igångsättning. Studie III och IV är kvalitativa intervjustudier där data analyserades med fenomenologisk respektive hermeneutisk livsvärldsmetod.
Resultatet av SWEPIS visade att inga perinatala dödsfall skedde i den tidiga igångsättningsgruppen men sex foster/barn dog i den sena gruppen. Det var ingen skillnad mellan grupperna avseende det primära utfallet i övrigt för det nyfödda barnet. Igångsättning i vecka 41 ökade inte risken för kejsarsnitt eller instrumentell vaginal jämfört med igångsättning i vecka 42. Risken för vård på neonatal avdelning, nyföddhetsgulsot, låg födelsevikt (liten för tiden) och hög födelsevikt (stor för tiden = $\geq$ 4500 g) var däremot högre för barnen i gruppen med sen igångsättning. I gruppen med tidig igångsättning fick fler kvinnor infektion i livmodern efter förlossningen.
Resultaten från de kvalitativa intervjustudierna visade att kvinnorna var i ett tillstånd av limbo, ett tomrum som kännetecknades av motsägelse i förhållande till förlossningen, till tillståndet de befann sig i, och till behandlingen från vårdgivarna. Kvinnorna upplevde dessutom tiden då de väntade på förlossningen som början av en resa på okända vatten. Sammanfattningsvis visar resultaten en lägre perinatal mortalitet vid igångsättning vid 41 graviditetsveckor jämfört med exspektans och igångsättning vid 42 veckor utan att det medför några allvarliga medicinska risker för kvinnan. De gravida kvinnorna behöver tydlig information och stöd för att stärkas vid övergången från att vara gravid till att föda.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Elden, H., Hagberg, H., **Wessberg, A**., Sengpiel, V., Herbst, A., Bullarbo, M., Bergh, C., Bolin, K., Malbasic, S., Saltvedt, S., Stephansson, O., Wikström, A-K., Ladfors, L., Wennerholm, U-B. Study protocol of SWEPIS a Swedish multicentre register based randomised controlled trial to compare induction of labour at 41 completed gestational weeks versus expectant management and induction at 42 completed gestational weeks. BMC Pregnancy and Childbirth BMC series – open, inclusive and trusted 201616:49

II. Wennerholm U-B.*#, Saltvedt, S.*, **Wessberg**, **A.**, Alkmark, M., Bergh, C., Fadel, H., Ladfors, L., Sengpiel, V., Wennergren, G., Wesström, J., Wikström, A-K., Elden, H.**, Stephansson, O.**, Hagberg, H.** Induction of labour at 41 weeks versus expectant management until 42 weeks (the Swedish postterm induction study - SWEPIS), a multicentre, open label, randomised, superiority trial. Submitted

III. **Wessberg**, **A**., Lundgren, I., Elden, H. Being in limbo: Women's lived experiences of pregnancy at 41 weeks of gestation and beyond - A phenomenological study. BMC Pregnancy Childbirth. 2017 Jun 2; 17(1):162

IV. **Wessberg**, **A**., Lundgren, I., Elden, H. Late-term pregnancy: Navigating in unknown waters – A hermeneutic study. Women and Birth, 2019 Apr 1. pii: S1871-5192(18)30244-0. [Epub ahead of print]

CONTENTS

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
DSMB	Data Safety Monitoring Board
e-CRF	Electronic Case Report Form
EDD	Estimated Due Date
GDPR	General Data Protection Regulation
GW	Gestational Weeks
HTA	Health Technology Assessment
ICM	International Confederation of Midwives
IUGR	Intra Uterine Growth Restriction
LMP	Last Menstruation Period
NICE	National Institute for Health and Care Excellence
NNT	Number Needed to Treat
PDA	Patient Data Act (*sv. patientdatalagen*)
R-RCT	Registry Randomised Controlled Trial
RCT	Randomised Controlled Trial
SFOG	Swedish Society of Obstetrics and Gynaecology
SU	Sahlgrenska University Hospital, Gothenburg, Sweden
SWEPIS	SWEdish Postterm Induction Study
WHO	World Health Organization

DEFINITIONS IN SHORT

e-CRF	Electronic Case Report Form, a tool for electronic collection of data (Bellary, Krishnankutty, & Latha, 2014).
Intrapartum stillbirth	Death of the foetus after onset of labour, after 22 completed gestational weeks (WHO, 2004).
Neonatal death	Death of newborn within the first 28 days, early neonatal death is from 0 – 7 days and late neonatal death is from 8 – 28 days (WHO, 2004).
Perinatal mortality	Includes stillbirth and early neonatal death (WHO, 2004).
Stillbirth	Death of the foetus in utero after 22 completed gestational weeks (WHO, 2004).

1 INTRODUCTION

This thesis is written from a midwifery perspective. In Sweden, midwives are independently responsible for prenatal, birth, and postpartum care in women with a normal pregnancy. Midwives are also involved in the care of the women when complications occur, which are managed by obstetricians. The care provided is individualised, which means that support and information is given according to the needs of the individual woman, and the midwife has to see and understand those needs (The Swedish Association of Midwives, 2018).

The length of the pregnancy is considered normal between 37 full gestational weeks to 41 gestational weeks plus 6 days, i.e. 260-294 days (ACOG, 2013; Fleischman, Oinuma, & Clark, 2010; Spong, 2013; WHO, 2004). It is well known that a late term pregnancy (≥41 gestational weeks) and postterm pregnancy (≥42 gestational weeks) is associated with increasing complications for both the mother and the infant. Around 15-20% of pregnant women reach late term, and 5-10% will reach post-term pregnancy (ACOG, 2013; WHO, 2004) (Olesen, Westergaard, & Olsen, 2003). As many as 14% of stillbirths globally occur in pregnancies lasting ≥42+0 gestational weeks i.e. postterm pregnancies (Lawn et al., 2016). There is insufficient scientific support regarding when to intervene with an induction of labour in a late or postterm pregnancy. There is also little research that is focused on women's experiences of a pregnancy lasting more than 41 completed gestational weeks.

This thesis has two research questions: the first question was to evaluate if a policy of induction of labour at 41 gestational weeks, i.e. early induction, is superior, in terms of perinatal and maternal outcomes, as compared to expectant management and induction at 42+0 gestational weeks (late induction), in healthy women with a low risk, singleton pregnancy. The second question was to get a deeper understanding and knowledge about women's experiences of ≥41 gestational weeks (late term pregnancy), as described during pregnancy and after birth.

The SWEdish Postterm Induction Study (SWEPIS) was done as interdisciplinary work, with both midwives and obstetricians involved in the care of the women who participated in the study. I hope that the results presented in this thesis will be useful for midwives, as well as for obstetricians, adding to our knowledge of the management of late term pregnancy, of women's experiences of late term pregnancy, and the roles of midwives in late term pregnancy care.

2 BACKGROUND

The background of this thesis consists of a brief history about dating the length of the pregnancy using Naegel's rule, definition of term, late and postterm pregnancy, and descriptions of the induction of labour methods that are used in clinical practice in Sweden. The background also includes data on risks for the neonate and the mother, a summary about current research in late and postterm pregnancy, women's experiences of pregnancy, induction of labour, and the concept transition, with the midwifery perspective as a theoretical framework. This is related to the three philosophical objectives of the ICM (ICM, 2014) , which are:

- "Pregnancy and childbearing are usually normal physiological processes"
- "Pregnancy and childbearing is a profound experience, which carries significant meaning to the woman, her family, and the community"
- "Midwifery care is emancipatory, as it protects and enhances the health and social status of women and builds women's self confidence in their ability to cope with childbirth"

In order to focus on childbearing as a normal physiological process in midwifery, knowledge about pregnancy complications is also needed.

2.1. Dating of pregnancy

For centuries, ten lunar or nine calendar months has been seen as the normal length of a gestation. In the New Testament, the length of gestation for the birth of Christ was defined as the time from the Feast of the Annunciation in March until Christmas day (Baskett & Nagele, 2000).

2.1.1. Naegel's rule

Historically, Hermann Boerhaave (1668-1738), a professor in botany and medicine at Leyden University, did the first gestational calculation and laid the foundation for Naegel's rule (Boerhaave, 1744: 437). In the early 1800s, Franz Carl Naegel (1778-1851), a professor of obstetrics at the University of Heidelberg, started to use the rule based on the calculations of Boerhaave (Baskett & Nagele, 2000).

Naegel's rule assumes a 28-day ovulation cycle and ovulation on day fourteen. To find the expected date of delivery, we start by adding seven days to the first day of the last menstruation, then count back three months, and finally add one

year (Baskett & Nagele, 2000; Loytved & Fleming, 2016). Historically, variations of the rule have been used, for example, at the end of the 19th and in the early 20th century, sometimes five instead of seven days was added to the first day of the last menstruation (Berkeley & Bonney, 1921: 16; Curtis, 1933: 709; Williams, 1903). Naegel's rule is still important, especially in developing countries where not all pregnant women can be examined by an ultrasound to determine the estimated due date.

2.1.2. Definition of pregnancy length

The definition of term pregnancy is described as a pregnancy lasting from 37 gestational weeks plus 0 days, to 41 gestational weeks plus 6 days, i.e. 260-294 days (ACOG, 2013; Fleischman et al., 2010; Quinn et al., 2016; WHO, 2004). A common notation is to combine the number of weeks and days and write 37+0 to 41+6 gestational weeks.

A postterm pregnancy is defined as a pregnancy lasting more than 42 full gestational weeks, or 42+0 (ACOG, 2013; Spong, 2013; WHO, 2004). Neonatal mortality and morbidity differs according to the length of the pregnancy, thus, pregnancy duration has been divided into subgroups (Fleischman et al., 2010; Reddy et al., 2011; Spong, 2013). The definition of term pregnancy has also been modified in several sub-groups (ACOG, 2013; Fleischman et al., 2010; Quinn et al., 2016; WHO, 2004). See current definitions of pregnancy lengths in Table 1.

Table 1. Definitions of pregnancy lengths

Definition:	Gestational weeks + days
Extremely preterm	< 28
Very preterm	28+0 - 31+6
Moderate or late preterm	32+0 - 36+6
Early term	37+0 - 38+6
Full term	39+0 - 40+6
Late term	41+0 - 41+6
Postterm	≥ 42+0

2.1.3. Ultrasound examination

Ultrasound technology has been in use since the mid-1950s (Campbell, 2013), and during this time, there has been a huge leap in the development of the technology. At present, dating of the length of a pregnancy is based on a

clinical ultrasound examination. The most reliable dating is the one made in the first trimester (up to 13+6 gestational weeks), but it can also be done in the second trimester (up to 22 gestational weeks) (ACOG, 2017; Butt et al., 2014; Kalish et al., 2004). In Sweden, the policy is that the estimated due date is based on the ultrasound examination, even when information about the woman's last menstruation period is available (SFOG, 2014). The World Health Organization's (WHO) recommendation regarding ultrasound is to do the examination before 24 gestational weeks, if possible. In addition to the estimation of the length of the pregnancy and the due date, reasons to do a clinical ultrasound examination include the detection of multiple pregnancies, detection of foetal anomalies, reduction in the frequency of induction of labour, and improvement of the experience of the pregnancy by the woman (WHO, 2018a). For pregnancies with in vitro fertilization the calculation of the estimated due date should be based on the fertilisation date (Butt et al., 2014).

2.2. Aetiology

The aetiology of postterm pregnancy is still unknown (Shea, Wilcox, & Little, 1998). Currently, known risk factors for the women are a previous postterm pregnancy, primiparity, obesity, heredity, genetic influence, advanced maternal age, and a male foetus. The most commonly occurring factors, however, are maternal obesity and a first-degree relative who was born postterm. There are also some rare causes such as foetal anencephaly and foetal adrenal hypoplasia (Ayyavoo, Derraik, Hofman, & Cutfield, 2014; Bakketeig & Hoffman, 1983; Laursen et al., 2004; Nohr et al., 2009; Oberg, Frisell, Svensson, & Iliadou, 2013; Olesen et al., 2003; Olesen, Westergaard, & Olsen, 2006; Stotland, Washington, & Caughey, 2007). Finally, genetic factors from both the mother and foetus can have impact on the length of the pregnancy (Ayyavoo et al., 2014; Laursen et al., 2004; Lunde, Melve, Gjessing, Skjærven, & Irgens, 2007) .

2.2.1. Complications in postterm pregnancies

Neonatal complications related to postmaturity include asphyxia, meconium aspiration syndrome, pneumonia, umbilical cord complications, convulsions, sepsis, shoulder dystocia, peripheral nerve damage, and traumatic injuries. The risks are higher in babies born postterm compared to babies born at term (AOR 1.1-2.0) (Olesen et al., 2003; Roos, Sahlin, Ekman-Ordeberg, Kieler, & Stephansson, 2010). Further, globally 14% of stillbirths occur in postterm pregnancies i.e. pregnancies ≥42 gestational weeks. It is noticeable that in these stillbirths, 5.5 of the 14% comprise births occurring in southern Asia and 6% in sub-Saharan Africa (Lawn et al., 2016).

Maternal complications include prolonged labour, postpartum bleeding, puerperal infections, emergency caesarean sections, and cervical lacerations. A risk factor is the disproportion between the foetal head and the mother's pelvis (Olesen et al., 2003).

2.3. Induction of labour in pregnancies ≥41 gestational weeks

To date, there is no consensus and there are no commonly agreed guidelines on how to manage pregnancies lasting 41+0 to 42+0 gestational weeks in women with an expected low risk, singleton pregnancy.

2.3.1. Randomised controlled trials

A large number of randomised controlled trials (RCT) have been conducted comparing induction at, or beyond, term, with expectant management, i.e. awaiting spontaneous onset of labour, with or without foetal surveillance. When SWEPIS was planned, most of the published studies had low methodological quality and lacked statistical power to be able to present evidence for either mode of management.

A multicentre, randomised controlled trial in Canada in 1992 included 3407 women, who were randomised to either induction at ≥41 gestational weeks or expectant management with surveillance until a spontaneous start of labour (Hannah et al., 1992). However, induction was performed if maternal and/or neonatal complications occurred, and in pregnancies lasting 44+0 gestational weeks. Perinatal mortality was low and similar in both groups, but the rate of caesarean section was significantly lower in the group that was induced at 41 gestational weeks. In addition, even though many women were included in the study, it has been criticised since different induction methods were used in the two groups.

Another randomised controlled trial from Norway included 508 women (Heimstad, Skogvoll, et al., 2007), who were randomised to either induction at 41+2 gestational weeks or surveillance and induction at 42+6 gestational weeks. This study did not show any difference in neonatal morbidity between the induction groups and the expectant management group and no difference in the mode of delivery.

A randomised controlled trial from the UK (the "35/39" study) (Walker et al., 2016) included pregnant women of 35 years or older, who were randomised to

either induction of labour at 39+0 to 39+6 gestational weeks, or expectant management and induction at 41+0 to 42+0 gestational weeks. The name of the study, 35/39, refers to the age of the included women and the gestational week at randomisation. The primary outcome was the rate of caesarean sections. The result did not show any difference in the rate of caesarean sections, neonatal or maternal outcomes, or childbirth experiences between the groups.

A randomised controlled multicentre trial from the USA (ARRIVE study) (Grobman et al., 2018) included 6106 nulliparous women with a low risk pregnancy. The two groups were randomised to either induction of labour in 39+0 gestational weeks to 39+4 gestational weeks, or expectant management and induction at 40+5 to 42+2 gestational weeks. The result showed no difference between the two groups in primary outcome, which consisted of a composite of severe neonatal complications and perinatal mortality. The rate of caesarean section was significantly lower in the induction group (19% versus 22%).

Only two randomised controlled trials have specifically compared induction at 41 gestational weeks to expectant management and induction at 42 gestational weeks (Gelisen et al., 2005; Keulen et al., 2019). A total of 600 women were included in the trial, which was performed in Turkey (Gelisen et al., 2005). In all, 300 women were randomised to induction at 41 gestational weeks and 300 women were randomised to expectant management and induction at 42 gestational weeks. The result showed no significant difference in neonatal outcomes between the groups. There were significantly higher rates of meconium aspiration syndrome (p=0.03), meconium stained amniotic fluid (p=<0.001), macrosomia (p=<0.001), and shoulder dystocia (p=0.03) in the expectant management group.

In the INDEX trial from the Netherlands (Keulen et al., 2019), the total number of women included was 1801, where 900 women were randomised to induction at 41 gestational weeks and 901 to expectant management and induction at 42 gestational weeks. The results showed a significantly higher risk for adverse perinatal outcomes in the expectant management group (p=0.045). This included a higher rate of babies with an Apgar score of <7 at 5 minutes (p=0.038), and higher birth weight (p=0.005).

A review by Gulmezoglu et al. (Gulmezoglu, Crowther, Middleton, & Heatley, 2012) included 22 RCTs (n=9383 women) showed a lower rate of perinatal deaths, meconium aspiration syndrome, and caesarean sections in the induction group compared to the expectant management group, but no difference in

number of babies admitted to the intensive care unit in the two groups. Middleton et al. (2018) included 30 RCTs in the most recent Cochrane review (n=12,479) (Middleton, Shepherd, & Crowther, 2018). Of 30 included studies, there were only two studies that compared induction at 41 gestational weeks versus 42 gestational weeks (Gelisen et al., 2005) (Keulen et al., 2019).

Table 2 presents a summary of the outcomes of induction of labour at or beyond term versus expectant management in systematic reviews and meta-syntheses of randomised controlled trials (Crowley, 2000; Gulmezoglu et al., 2012; Hussain, Yakoob, Imdad, & Bhutta, 2011; Middleton et al., 2018; Myers et al., 2002; Rydahl, Eriksen, & Juhl, 2019; Sanchez-Ramos, Olivier, Delke, & Kaunitz, 2003; Wennerholm, Hagberg, Brorsson, & Bergh, 2009; Wood, Cooper, & Ross, 2014).

Table 2. Systematic reviews and Cochrane reviews of outcomes of induction of labour at or beyond term versus expectant management.

Authors/Years	**Number of included RCTs.** **Number of women, n**	**Purpose/Objectives**	**Years of publication of the studies/Gestational weeks**	**Result/Conclusion**
Crowley P, 2000 Cochrane review	26 n=not stated	To assess the interventions effect on either improve the outcomes or reduce the incidence of post-term pregnancy	1978 – 1995 37 - ≥42	IOL after 41 GWs reduced perinatal mortality (OR 0.20, 95% CI 0.06 - 0.70, no difference in the rate of caesarean section. Early routine ultrasound reduced the rate of postterm pregnancy (OR 0.68, 95% CI 0.57 - 0.82). Breast and nipple stimulation had no impact on the rate of post-term pregnancy (OR 0.52, 95% CI 0.28 - 0.96.
Myers, E. R. Blumrick, R. Christian, A. L. Santanu Datta, S. Gray, R. N. Kolimaga, J. T. Livingston, E.	15 (17 publications on 15 trials) n=not stated	To review the evidence of strategies to prevent the maternal and foetal risks at ≥ 40 GW	1983 – 1997 ≥38 weeks	The rate of perinatal death was lower with elective induction after 41 GW vs. surveillance and expectant management. To prevent one death, 500 inductions were needed.

Lukes, A. Matchar, D. B. McCrory, D. C., AHRQ, 2002, Systematic review				
Sanchez-Ramos, L. Olivier, F. Delke, I. Kaunitz, A. M., 2003, Systematic review and meta-analysis	16 n=6,588	To review elective induction at ≥41 GW compared to expectant management	1969 – 2002 ≥41 GW	There was no significant difference in perinatal mortality and stillbirth between induction at 41 GW and expectation management (0.09% vs. 0.33%) (OR 0.41; 95% CI 0.14, The rates of caesarean section decreased with elective induction at 41 GW, vs. expectant management (20.1% versus 22.0%)
Wennerholm, U. B. Hagberg, H. Brorsson, B. Bergh, C., 2009, Systematic review and meta-analysis	13 n=6,708	To compare elective induction versus expectant management at ≥41 GW, outcomes: maternal and perinatal	1987 – 2007 ≥41 GW	No significant difference was shown in perinatal mortality between induction at 41 GW and expectation management (RR: 0.33; 95% (CI): 0.10_1.09). Significant lower rate of meconium aspiration syndrome was shown in the elective induction group (RR: 0.43; 95% CI: 0.23-0.79). Higher rate of caesarean section was shown in the expectant management group. (RR: 0.87; 95% CI: 0.80-0.96)
Hussain, A. A. Yakoob, M. Y. Imdad, A. Bhutta, Z. A., 2011, Systematic review and meta-analysis	25 studies in the review, 14 RCTs in the meta-analysis n=6,597	To compare IOL at ≥41 GWs versus expectant management on the outcome stillbirth	1969 – 2007 ≥41 GW	There were fewer perinatal deaths (RR=0.31; 95% CI: 0.11-0.88 in the induction group at ≥ 41 GW vs. the expectant group, no significant difference was found in number of stillbirths (RR= 0.29; 95% CI: 0.06-1.38)in stillbirth
Gulmezoglu, A. M. Crowther, C. A.	22	To assess IOL at term or beyond with expectant	1975 -2007 37 - ≥41 GWs	IOL was associated with fewer perinatal deaths (all-cause) (RR) 0.31, 95%

Middleton, P. Heatley, E., 2012, Cochrane review	n=9,383	management and waiting on spontaneous start of labour or IOL on maternal or foetal indication, outcomes for the infant and the mother	One trial induced 37-39 GWs, three trials induced 39-40 GWs, one trial induced <41 GWs, four trials induced at 41+0 GWs, 13 trials ≥41 GWs	(CI) 0.12-0.88 vs. expectant management. In the induction group, there was one perinatal death and in the expectant management group, there were 13 deaths. MAS in the induction group were lower (RR 0.50, 95% CI 0.34-0.73 then in the expectant group. Lower rates of caesarean section in the induction group (RR 0.89, 95% CI 0.81-0.97) vs. expectant management group. NNT was 410 to prevent one perinatal death (95% CI 322 -1492).
Wood, S. Cooper, S. Ross, S., 2014, Systematic review and meta-analysis	37 trials in the review 31 trials in the meta-analyses n=13,045	To assess IOL impact on the outcome caesarean section among women with intact membranes	1969 - 2012 37 –42 GWs, 27 trials with induction vs expectant management 37-42 GWs, 10 trials with i.e. suspect macrosomia, twins, SGA, high risk for caesarean section	19 trials assessed pregnancies ≥41 GWs pregnancies and 12 trials with induction for other reasons i.e. such as macrosomia, twins, SGA. The risk of caesarean was reduced with a policy of IOL compared with expectant management (OR 0.83, 95% CI 0.76–0.92).
Middleton, P. Shepherd, E. Crowther, C. A., 2018, Cochrane review	30 n=12,479	To assess IOL at term or beyond with expectant management and waiting on spontaneous start of labour or IOL on maternal or foetal indication, outcomes for the infant and the mother	1975 - 2016 37 - >42 GWs, 10 trials induced at <41 weeks, 19 trials induced at ≥41 weeks, one trial induced between 37-42 GWs	With induction, fewer perinatal deaths (all-cause) (RR) 0.33, 95% (CI) 0.14-0.78, in the induction group were two perinatal deaths and the expectant management group 16 perinatal deaths. NNT to prevent one perinatal death was 426 (95% CI 338-1337). One IUFD in the induction group and ten in the expectant management group. Fewer neonates needed care at NICU and hade low AS <7 at five minutes in the induction group. For the mother, there were fewer caesarean sections in the induction

				group (RR 0.92, 95% CI 0.85-0.99.
Rydahl, E. Eriksen, L. Juhl, M. 2019 Systematic review	7 n=361,457	To assess The effects of IOL prior to post-term on the mother and foetus. Maternal and foetal outcomes after routine IOL in low-risk pregnancies at 41+1-6 vs. IOL at 42+ 1-6 GWs.	2005-2013 ≥ 41 GWs 2 RCT , 2 quasi-experimental trials 3 cohort study	An increased risk of caesarean section (RR 1.11, 95% CI 1.09–1.14), caesarean section due to failure to progress (RR 1.43, 95% CI 1.01–2.01) at IOL 41+1-6 GWs even increased risk for labour dystocia, uterine rupture, pH <7,10, precipitate labour, and decreased risk for oligohydramnios and meconium stained fluid compared to IOL at 42+1-6. Lacked power to assess perinatal death.

CI = Confidence Interval
GW = Gestational Weeks
IOL = Induction of Labour
NNT = Number Needed to Treat, number that needs to be treated to reduce outcome by one
OR = Odds Ratio, the odds that an outcome will occur in an exposed group, compared to the odds of the outcome occurring in the absence of that exposure
RR = Risk Ratio, the ratio of probability of outcome in an exposed group to the probability in an unexposed group
SGA = Small for Gestational Age

At the Sahlgrenska University Hospital (SU), Göteborg, Sweden, a Health Technology Assessment (HTA) was performed that included 13 RCTs (n = 6617 women) (Wennerholm et al., 2009). The analysis showed significantly fewer cases of meconium aspiration syndrome and a lower rate of caesarean section in the induction group versus the expectant management group, and no difference in perinatal mortality between the two groups. In 2012 an updated version of the HTA (Wennerholm et al., 2012) was done and in this version 17 RCTs were included (n=7223 women). This review showed fewer cases of meconium aspiration syndrome and a lower rate of perinatal mortality in the induction group. However, in the expectant management group many of the adverse neonatal outcomes occurred after 42+0 gestational weeks.

In conclusion, there appears to be an advantage with induction at 41 gestational weeks for both the mother and the foetus/neonate, but more trials are necessary to answer the specific question whether to induce labour in gestational week 41 or 42 in a postterm pregnancy. As discussed above, only two previous trials have compared induction of labour at 41 weeks compared to 42 gestational weeks.

2.3.2. Register-based studies

In addition to the RCTs, a number of register-based retrospective epidemiological studies have been published.

A retrospective study based on the nationwide Swedish Medical Birth Registry (Grunewald, Hakansson, Saltvedt, & Kallen, 2011) investigated neonatal morbidity after a regional change in 2005 in induction policy for postterm pregnancy in the Stockholm region in Sweden. The time for induction was changed from 43+0 to 42+0 gestational weeks. The counties in Sweden were divided into three groups according to the number of pregnant women with a gestational length of more than 42+2 gestational weeks among all pregnant women who reached more than 41+2 gestational weeks. Group 1 received the most active management and hence had the lowest number of postterm pregnancies with the induction of labour. The group with the least active management was group 3, and group 2 was intermediate. No unit practiced mandatory induction before 42+0 gestational weeks. Stockholm County was analysed separately due to a change in the guidelines for management in 2005. Two periods were compared: 2000 – 2004 versus 2005 – 2007. There was no difference in neonatal outcomes between group 1 and 3 during 2000 – 2004. For 2005-2007, the risk for perinatal morbidity was significantly reduced with a more active management. The result showed 48% lower rates of perinatal death and a decreased rate of neonatal morbidity in the Stockholm region after changing of time for induction to 42 gestational weeks, instead of at 43 gestational weeks.

In another register-based study, which also used the Swedish Medical Birth Registry (Lindegren, Stuart, Herbst, & Kallen, 2017), the counties of Sweden were divided into three groups based on proportion of the numbers of pregnancies ≥42+3 gestational weeks. Group 1 had the lowest rates of postterm pregnancies and the most active management (<12.6 % proceeding to 42+3 weeks). Group 3 had highest rates of postterm pregnancies and the least active management (>17.6 % proceeding to 42+3 weeks). The results showed that, based on all pregnancies that reached ≥41+3 gestational weeks, there was an advantage for primiparas with more active management, compared to expectant management. The data from the Swedish Medical Birth Registry showed an increased risk of neonatal morbidity such as meconium aspiration syndrome and low Apgar score <7 at 5 minutes for primiparas at the units with the most expectant management, compared to units with more active management. The result showed a higher risk of caesarean sections for both primiparas and multiparas with a more active management of labour compared to expectant management of labour.

A register-based national cohort study from Denmark (Zizzo, Kirkegaard, Pinborg, & Ulbjerg, 2017) showed a decreased rate of stillbirth and perinatal neonatal mortality among low risk pregnancies, after change to a more active management of pregnancies at 41 gestational weeks with addition of some kind foetal surveillance at 41+0 gestational weeks. Women with a body mass index >35 kg/m^2 or who were 40 years of age or above, were induced at 41+0 gestational weeks. The rates of caesarean sections and vacuum extractions did not increase, even if the induction rate increased from 28.2 % to 42.6%.

In conclusion, the register-based studies showed an increased risk for perinatal and maternal complications in postterm pregnancies compared to labours at term and that this risk tended to decrease if the pregnancies were induced at earlier gestation.

Table 3 presents a summary of neonatal outcomes and maternal outcomes for term and post-term pregnancies in non-randomised register-based studies (Campbell, Ostbye, & Irgens, 1997; Grunewald et al., 2011; Heimstad, Romundstad, & Salvesen, 2008; Hilder, Costeloe, & Thilaganathan, 1998; Ingemarsson & Kallen, 1997; Kortekaas et al., 2015; Lindegren et al., 2017; Maoz, Wainstock, Sheiner, & Walfisch, 2018; Olesen et al., 2003; Zizzo et al., 2017).

Table 3. Register-based, non-randomised studies of neonatal and maternal outcomes for term and postterm pregnancy.

Authors/Years	**Years, population/ EDD/country**	**Purpose/ Objectives**	**Study design**	**Result / Conclusion**
Campbell MK, Ostbye T, Irgens LM., 1997	1978 – 1987, Norway, All singleton birth, term n = 379,445 and post-term n=65,796. (completed GW was based on LMP), Norway	To identify factors associated with post-term birth and factors associated with adverse outcomes in postterm births.	10-year cohort, Medical Birth Register of Norway	The risk for perinatal mortality were slightly increased (RR) 1.11; 95% (CI) 0.97, 1.27) in post-term pregnancies. SGA and mothers age ≥ 35 years are risk factors for perinatal mortality, SGA (RR 5.68; 95% CI 4.37, 7.38) respectively ≥35 years (RR 1.88; 95% CI 1.22, 2.89), Being LGA was related to maternal complications, and being SGA with foetal complications.

Ingemarsson I, Kallen K, 1997	1982-1991 All singleton deliveries at 38-43 GWs, n=914,702 of which n=76,761 are deliveries ≥ 42 GWs, Pregnancy length based LMP, ultrasound, manual examination, Sweden	To study stillbirths and neonatal mortality in the postterm period.	Swedish Medical Birth Registry (MBR). Cause of Death register.	A slightly higher risk for IUFD was shown at ≥42 GWs versus 40 GWs for primiparas, OR increased from 1.50 to 1.79. There was no difference in IUFD for multiparas. For both primiparas and multiparas, there was a higher risk for neonatal death after 42 GWs (OR 1.61).
Hilder L, Costeloe K, Thilaganathan B., 1998	1989-1991, All pregnancies from 20 – 45 GWs, pregnancy length based on ultrasound or maternal history, n=171,527, London	To evaluate the rates of stillbirth and infant mortality per 1000 total or live births and ongoing pregnancies at each given gestation.	Retrospective study, registered births in North East Thames Region, London 18 hospitals	The rates of IUFD increased from 1.7 ‰ at 41 GWs to 1.9 ‰ at 42 GWs, and 2.1 ‰ at ≥43 GWs. The risk of stillbirth, post-neonatal, and neonatal death increased significantly after ≥42 GWs.
Olesen AW, Westergaard JG, Olsen J., 2003	1978-1993, All women with singleton live-born infant with postterm delivery n=77, 956, a reference group, 5% of random women with spontaneous term deliveries n=34,140, based on LMP or ultrasound, Denmark	To estimate the risk of foetal and maternal complications associated with postterm delivery in Denmark.	A cross-sectional study, Danish Medical Birth Registry and the Danish Discharge Register	There was an increased risk for asphyxia before, during, and after labour, meconium aspiration, bone fracture, cord complications, pneumonia and septicaemia for the foetus/neonate (aOR between 1.4 and 2.0). There was an increased risk for cephalopelvic disproportion, post-partum haemorrhage, dystocia, cervical rupture, intrapartum death, caesarean section, and puerperal infection for the mother (aOR between 1.2 and 3.1).

				There was a significantly higher risk for perinatal death (IUFD and neonatal death day 1-7) (OR 1.36 [1.08-1.72]) in the postterm group. There was no difference in IUFD between the groups (OR 1.24 [0.93-1.66]). >12% of the postterm deliveries was after 43+0 GW
Heimstad R, Romundstad PR, Salvesen KA., 2008	1999-2005, All singletons birth beyond 41 weeks, based on ultrasound in second trimester around 18 GWs, (n=408,631), Norway,	To assess risk estimates for foetal and perinatal deaths day by day beyond 41 completed weeks and to estimate numbers needed to induce to avoid 1 foetal or perinatal death.	Retrospective register study, The Norwegian Medical Birth Registry	Perinatal death increased with increasing gestational age (0.18 ‰ at day 287 to 5.1 ‰ at day ≥302, (p=0.001). NNT to prevent 1 IUFD was 671 (95% CI: 571-794) at day 287, and 195 (95% CI: 84-600) at ≥302 days (p=0.004). NNT to prevent 1 perinatal death was 527 (95% CI: 457-612) at day 287, and 195 (95% CI: 84-600) at ≥302days (p=0.02). NNT is high (671-195), beyond 41 GWs the NNT decreases constantly.
Grunewald C, Håkansson S, Saltvedt S, Källén K., 2011	2000-2007 All singleton pregnancies ≥41+3 n=119,198, based on ultrasound in second trimester Sweden	To evaluate the effects on neonatal morbidity of a regional change in induction policy for post-term pregnant from 43+0 to 42+0 GWs.	Retrospective register study, Swedish Medical Birth Registry,	The counties divided in three groups based on the number of pregnancies 42+2 GWs. Group 1 had the lowest rates of postterm pregnancies, and the most active management. Group 3 had highest rates of postterm pregnancies, and least active management.

				Stockholm county was analysed by itself due to a change in the management in 2005; two periods were compared: 2000 – 2004 versus 2005 – 2007. There was no difference between groups one and three in 2000-2004 for neonatal outcomes. For 2005-2007 there was an increased risk for meconium aspiration (p=0.036). The perinatal morbidity was significantly reduced with a more active management of pregnancies >41+2 gestational weeks.
Kortekaas JC, Kazemier BM, Ravelli AC, de Boer K, van Dillen J, Mol B, et al., 2015	1999-2007 Singleton pregnancy between 37+0-42+6 GWs and have had a previous pregnancy with a length of 37+0-42+6 GWs n=233,327, Netherlands	To assess the recurrence rate of postterm delivery (gestational age at or beyond 42 + 0 weeks or 294 days) and to describe maternal and perinatal outcomes after previous postterm delivery.	A national cohort study the perinatal database from the Netherlands Perinatal Registry.	There was a 15% risk of having postterm pregnancy if the first pregnancy was postterm, compared to a 4% risk with term delivery in the first pregnancy, aOR 4.2 (95%CI 4.0–4.4, p < 0.0001). No difference for perinatal and maternal outcomes was shown between women that had a postterm pregnancy as primiparas and women that were multiparas when they had a postterm pregnancy.
Lindegren L, Stuart A, Herbst A, Kallen K., 2017	2001-2013 All singleton cephalic pregnancy ≥41+3 GWs (290 days) delivered at centres s with	To compare maternal and foetal outcomes depending on the timing of delivery in prolonged pregnancies	The Swedish Medical Birth Register. Three time periods in the study (2001–05, 2006–09, and	There was a higher risk (30%) for neonates to primiparas at clinics with the most expectant management to have adverse perinatal outcomes (meconium aspiration,

	>500 deliveries/year. n=199,770, Sweden	among primiparas and multiparas separately.	2010–13), Three groups of hospital from the less active management to the most active management.	AS <7 at five minutes, and perinatal death). For meconium aspiration and perinatal death OR 1.26 (95% CI 0.94–1.69, p=0.12) for primiparas and 1.42 (95% CI 1.13–1.79, p=0.003) for multiparas. However, there was no difference in multiparas for in the neonatal outcomes. The NNT is 180 to prevent adverse perinatal outcomes. Active management increased the risk for caesarean section for both primiparas and multiparas.
Zizzo AR, Kirkegaard I, Pinborg A, Ulbjerg N., 2017	2008 - 2014 n=102,167 singleton deliveries at ≥41+0 GWs, compared 2008-2010 vs. 2012-2014 after new guidelines 2011, based by ultrasound, Denmark	To investigate if the changes in management of post-date pregnancies have reduced perinatal mortality and morbidity, and if these changes have any impact on the risk of obstetric complications in pregnancies at or beyond 41+0 gestational weeks.	Cohort study Danish Medical Birth Registry, deliveries in Denmark	The risk for IUFD declined from 0.9% in 2008-2010 to 0.5% in 2012-2014. (aOR 0.50, 95% CI 0.29–0.89, p =0.018). Perinatal death declined from 58 (1.3%) in 2008–2010 to 33 cases (0.8%) in 2012–2014 (aOR 0.62, 95% CI 0.39–0.96, p=0.033). The risk for vacuum extraction and caesarean section were stable in spite of the higher rates of induction.
Maoz O, Wainstock T, Sheiner E, Walfisch A, 2018	1991-2014 All singleton deliveries, one hospital, n=226,918, 95,9 % were term n= 217,544 and 4.1% were postterm n=9374,	To investigate whether postterm pregnancy increases the risk for adverse perinatal outcome.	Cohort study. Compare deliveries (37+0 – 41+6 with ≥42+0 GWs.	There were higher rates of complications in postterm pregnancy ≥42 GWs, with significantly more cases of meconium stained amniotic fluid, labour induction, failed induction, oligohydramnios, caesarean hysterectomy, shoulder dystocia,

	Based on LMP and ultrasound Israel			postpartum haemorrhage, macrosomy (11.5 versus 4.7%, p<.001) and low Apgar score <7 at 1-min (6.5 versus 4.4%, p<.001). There was a significant lack of prenatal care (11.5 versus 8.8%, p<.001) in the postterm group. In the postterm group, twice as common with total perinatal death (IUFD, intrapartum death, postpartum death) (0.4 versus 0.2%, p<0.001), especially intrapartum death and IUFD.

CI = Confidence Interval
GW = Gestational Weeks
IUFD = Intrauterine Foetal Death
NNT = Number Needed to Treat to prevent for example one perinatal death.
OR/aOR = Odds Ratio, the odds that an outcome will occur in an exposed group, compared to the odds of the outcome occurring in the absence of that exposure
RR = Risk Ratio, the ratio of probability of outcome in an exposed group to the probability in an unexposed group

2.4. Induction methods in postterm pregnancies

The induction of labour is an artificial start of labour. There are different methods for induction of labour, including mechanical/non-pharmacological, pharmacological, or complementary methods. The choice of methods depends on national and local guidelines (Alfirevic et al., 2016; Mozurkewich et al., 2011; NICE & Excellence, 2008; WHO, 2018b). The physiological process of softening of the cervix usually starts a few weeks before labour begins. The choice of induction method is also dependent on the clinical status of the woman; primarily on how prepared the cervix is for labour, as assessed by the Bishop score. The Bishop score ranges from 0-10, where a lower score indicates that the cervix is less favourable and a higher score that it is more favourable. When the score is <6, the cervix is usually assessed as unfavourable. (SFOG, 2016; Tenore, 2003).

2.4.1. Mechanical/non-pharmacological methods

Mechanical methods for induction of labour have been used for many years and are commonly used when the cervix is assessed as unfavourable. The mechanism of mechanical methods is to apply pressure on the inner os of the cervix that stimulates the release of prostaglandin in the tissue, which in turn likely increases both oxytocin and further prostaglandin secretion. The mechanical method used depends on the Bishop score and the clinical status on the woman (Alfirevic et al., 2016; Mozurkewich et al., 2011; SFOG, 2016).

Commonly used mechanical and non-pharmacological methods:

- Membrane sweep or membrane stripping: this method aims to separate the membranes from the cervix, which stimulates release of prostaglandin, to start the labour process. For this to be possible, the cervix must have started to dilate.
- Amniotomy: artificial rupture of the membranes. The membranes are broken with an amniohook. This is possible when the cervix has softened and started to dilate. The head of the foetus increases the pressure on the inner os, which increases the release of the hormones that can start intrauterine contractions.
- Catheter with a single or double balloon: a specialised catheter is inserted into the cervical canal. The balloon is filled with saline and pressure is applied by pulling the catheter in intermittent intervals, which aims to enhance the release prostaglandin. The catheter can remain in place for 12-24 hours. When the cervix is dilated 3-4 cm, the catheter with its balloon will fall out, and the next step in the induction process is an amniotomy.

2.4.2. Pharmacological methods

The body naturally produces prostaglandins, which are important for the start of the labour process, to ripen the cervix, and to stimulate uterine contractions. Prostaglandins are lipids that are naturally present in the body as e.g. PGD_2, PGE_2, PGF_2, and PHI_2. All prostaglandins have different mechanisms on different organs in the body. PGE_2 (dinoproston) and PGF_2 are both involved in the start of the labour, with effects on uterine contractility, rupture of the membranes, and the ripening of the cervix. The prostaglandins PGE_1 (misoprostol) and PGE_2 are used for induction of labour in the third trimester when there is need for cervical ripening. The primary effect in an induction of labour is the effect on the cervix (SFOG, 2016).

Synthetically produced prostaglandin has been used to ripen the cervix since the 1960s (Alfirevic et al., 2016). Prostaglandins can be administered in various ways e.g. vaginally, intracervically, or orally (Alfirevic, Devane, & Gyte, 2013; SFOG, 2016; WHO, 2018b).

Oxytocin is a peptide hormone produced in the hypothalamus in the brain, and secreted from the posterior pituitary gland. It has effects on cervical dilation, and promotes uterine contractions during the later stages of labour. Oxytocin also has a large number of physiological effects in the body and brain, not related to childbirth (Romano, Tempesta, Micioni Di Bonaventura, & Gaetani, 2015) .

Commonly used pharmacological methods:

- Misoprostol: Cytotec® (or equivalent), administrated orally.
- Dinoproston (synthetic prostaglandin E2): Propess pessary® (a small tampon), inserted in the fornix of the vagina.
- Dinoproston (synthetic prostaglandin E2): Minprostin®, cervical gel, inserted in the fornix of vagina.
- Oxytocin: synthetic oxytocin administered by intravenous infusion. The drip rate is increased until the woman has an established labour progress. Oxytocin is normally not administered until the cervix is softer and has started to dilate.

2.4.3. Complementary methods

There are several complementary methods, but they are not commonly used. Acupuncture is not generally accepted and used as a method for induction. Oral consumption of Castor oil is an old method. Breast stimulation may release oxytocin and start uterine contractions. Sexual intercourse may help as semen contains prostaglandin, although in a very small amount, and therefore has been hypothesised to promote the start of labour (Tenore, 2003; Wieland & Santesso, 2018) .

2.5. Women´s experiences of childbearing

In this section women's experiences of childbearing are described, which includes studies focusing on both pregnancy and birth. In a midwifery perspective, women's experiences of pregnancy and birth are important as this carries significant meaning to the women and their families (ICM, 2014) .

There are models of care that focus on women's experiences, i.e. woman-centred care, carried out in different countries and maternity care systems (Lundgren, Berg, Nilsson, & Olafsdottir, 2019). One such model has been developed in a Nordic context (Berg, Asta Olafsdottir, & Lundgren, 2012). This model, the Midwifery Model of Women-Centred care (MiMo) consists of five themes: "a birthing atmosphere", "reciprocal relationship", "grounded knowledge", "cultural context", and "a balancing act". Furthermore, the five themes are important for midwives to be aware of to be able to give a women-centred care, a care were the women and their personal needs are seen (Berg et al., 2012).

Labour and birth can be described as a life event, a complex process, and an individual event. This life event consists of physiological and psychological processes, which in turn are affected by policies and social, environmental, and organisational contexts (Larkin, Begley, & Devane, 2009). Three published reviews of studies of women's experiences have showed that, to have a positive birth experience, the women want to give birth in a trustful and safe environment. This trustful environment consists of continuous support during labour, support from a midwife or other health care provider or a companion, and personal information during the childbirth. To stay focused, the women want emotional support during the birth (Bohren, Berger, Munthe-Kaas, & Tunçalp, 2019; Downe, Finlayson, Oladapo, Bonet, & Gülmezoglu, 2018; Lunda, Minnie, & Benadé, 2018).

To be able to look forward to the forthcoming birth, the women need support from the midwives and inner strength. The support from midwives should consist of genuine interest, sufficient information, time, and the possibility to ask questions and have them answered (Gatward, Simpson, Woodhart, & Stainton, 2010; Hildingsson, 2014; Larsson, Warna-Furu, & Nasman, 2016).

A meta synthesis (Olza et al., 2018) was conducted on women's psychological processes during physiological childbirth. This highlighted the importance for the caregivers to see the women's personal needs during the birth process and to be able to support and empower the women during the birth. The person who is present during the birth has a substantial impact on the women and their experience of birth. The midwife's presence was seen as very important. The women wanted to have control, and when the labour got more intense, women could hand the control over to the midwives. The transition to motherhood is empowered by a physiological birth, supported by emphatic and supportive caregivers (Olza et al., 2018). The definition of normal physiological birth is a birth with a spontaneous start, normal progress during the labour, a vaginal

birth, and normal blood loss. This relates to the normal physiology of the body (Kennedy et al., 2015; Nurse-Midwives, 2012).

During labour, women can have contradictory feelings; they want the body to give birth, but at the same time, they want to remain in control of their body. The women may have a feeling that they are in a situation without any return. Here, the midwife can empower the women during the birth so that the women get a sense of control. The experience of strength, together with the pain, may give meaning in the transition from being a pregnant woman to motherhood (Lundgren, 2004; Lundgren, 2005).

The results from a Swedish study showed that experience and feelings of the birth was related to the length of the pregnancy. The women with a normal length of the pregnancy (38-41 gestational weeks) and spontaneous start of the labour had a less negative experience of the birth and more positive feelings compared to women who underwent an induction. For the women with pregnancy that lasted for more than 41 gestational weeks there was no difference between women with a spontaneous start and those who underwent induction (Hildingsson, Karlström, & Nystedt, 2011).

Negative birth experiences are shown to be related to medical interventions e.g. augmentation of labour, induction and operative delivery, obstetric analgesia, and a long duration of labour. The overall experience of birth became more negative if the baby was unhealthy. Other factors that gave a negative birth experience were anxiety and pain during labour (Waldenstrom, 1999). In a critical review, it was shown that pain could be seen as challenging and a paradox during the childbirth. The paradox was that the pain was necessary to be able to give birth, which could make the women accept and cope with the pain (Van der Gucht & Lewis, 2015). Positive birth experiences were associated with support from the midwife and/or the partner, the possibility to ask questions, a possibility to express feelings during labour, and feeling involved in the birth process (Waldenstrom, 1999). The support of women during childbirth leads to a more positive birth experience, with as minimal intervention as possible. (Taheri, Takian, Taghizadeh, Jafari, & Sarafraz, 2018). These results from the systematic review and meta-analysis (Taheri et al., 2018) support the results from Waldenström (Waldenstrom, 1999).

The results from a cross-sectional study from Canada (n=64219 women) showed that 9.3% of the women rated the birth as negative. Women older than 30 years of age had a two times higher rate of negative birth experiences, compared to younger women. Other factors that were associated with negative

birth experiences were poor self-perceived personal health and violence from the partner. Not attending the pre-birth classes and caesarean section increased the risk of negative birth experiences (Smarandache, Kim, Bohr, & Tamim, 2016).

2.5.1. Women's experiences of late and postterm pregnancy

One qualitative interview study from Denmark about postterm pregnancy discussed women's perception of time during the days after the estimated due date had passed. The women expressed that time was standing still and that the birth was even further away. They also experienced a feeling of losing the sense of being a pregnant woman without any medicalisation and, instead, they felt that they were seen as person who has passed their estimated due date with an induction on the schedule, and hence medicalised. They felt that they were categorised by the health care system according to the length of their pregnancy. The focus had changed from seeing the person, to a categorisation and stigmatisation of the pregnancy and to medical issues. This in turn led to the women feeling less involved when the pregnancy became postterm (Damkjær Maimburg, 2016).

In a study from Canada (Westfall & Benoit, 2004), it was found that women whose pregnancies lasted more than 40 weeks experienced physical, social, practical, and psychological implications for themselves, which were sufficient for the women to attempt labour induction on their own to prevent a postterm pregnancy. The women intervened by "doing-it-yourself" with e.g. castor oil, blue cohosh (a kind of root), homeopathic preparations, and sexual intercourse. Ayers et al. (2005) found that women who had not given birth at 41 weeks had more anxiety compared to women who had given birth at term (Ayers, Collenette, Hollis, & Manyonda, 2005).

In a review, Lou et al. (2018) showed that women in postterm pregnancy changed their expectations from a spontaneous start to induction of labour. Women also experienced that the physician made the decision for them and that they were not involved. Further, women experienced induction of labour as a process where they took one step at a time and that there was a lack of information before and during the induction of labour (Lou et al., 2018).

2.5.2. Women's experiences of induction

A systematic review by (Coates, Cupples, Scamell, & McCourt, 2019) showed that women trusted the clinicians when the decision was made about the induction, but they experienced that the decision was made without engaging

the women. The information about induction of labour was focused on the risks to proceed with the pregnancy. Some women felt a relief after the decision, where they wanted to finish the pregnancy, and the most important aspect was always the unborn child's health. The women did not feel prepared for the induction of labour, due to lack of information. During the induction of labour, women felt a lack of control, that they were not supported, and that they were just like a thing in the system, not a person (Coates et al., 2019). The experience of care has been reported to be less satisfying among women after induction of labour (Henderson & Redshaw, 2013; Hildingsson et al., 2011).

A study from Australia showed two different dimensions of women's experiences after they were booked for an induction due to postterm pregnancy. The first one was "Time is up". It was described as the time for being pregnant was up and a kind of relief when the plan for induction was in place. Another explanation was what the women felt that they needed to take the next step with the induction, when labour did not start spontaneously. The second dimension was "Shifting expectations", which they explained in terms of a shift from the original plan, with a spontaneous start of labour, to the induction of labour. They also expressed that they were lacking meaningful information during the time from the booking of the induction of labour and during the induction (Gatward et al., 2010).

The results among primiparas in a study from USA showed that women described their encounter with the clinician before the induction of labour as brief; they did not feel they could ask questions, and that the decision was made by the physician. The physician related to the baby's safety and, in this regard, they trusted the physician. The focus of the received information was on the logistics for an induction of labour, but they were lacking information regarding the possible risks involved and the opportunity to make an informed choice (Moore, Low, Titler, Dalton, & Sampselle, 2014).

To date, Heimstad et al. (Heimstad, Romundstad, Hyett, Mattsson, & Salvesen, 2007) have conducted the only RCT that assessed the women's experiences of induction versus expectant management in postterm pregnancy, using a questionnaire (n=508). The result showed that 74% of women would prefer an induction if they would have the opportunity to choose even if the induction process could lead to a more intensive labour ($p=0.001$). Of the women who underwent an induction, 84% had a positive birth experience.

In summary, the existing literature regarding women's experiences of late and postterm pregnancy, and the induction of labour, indicate that there is a lack of research about women's own experiences of pregnancy ≥41 gestational weeks.

The research that has been conducted has shown that the women feel like they are medicalised and categorised in the health care system. The length of the pregnancy has a social and physiological impact on them. They felt no involvement in the decision about the induction, but some felt a kind of relief when the day for induction was booked. One study showed that the majority of women would prefer an induction if necessary in an eventual next pregnancy.

2.5.3. Transition

Transition is defined as a result of changes in lives, relationships, environment, and health. Development and lifespan transitions such as pregnancy, childbirth, adolescence, parenthood, aging, and menopause may make a person vulnerable. Other such transitions are illness and experiences, such as surgical procedures, diagnosis, recovery, and rehabilitation. Other examples of transitions are social and cultural, e.g. retirement, family caregiving, and migration (Meleis, Sawyer, Im, Hilfinger Messias, & Schumacher, 2000). The transition to become a mother is one of the most common life transitions for women (Nelson, 2002). This starts with pregnancy, which can be seen as a journey or adventure. The bodily, psychological, and emotional changes that arise from changing hormone levels and a growing uterus are not only the effect of the pregnancy, it also helps the women with the transition from being pregnant to becoming a mother (Lothian, 2008). The maternal transition starts early in the pregnancy and is not complete before the woman has a feeling about control over the new situation, which can be some considerable time after becoming a mother (Darvill, Skirton, & Farrand, 2010). The pregnant woman and the new mother need support during the transition, e.g. support from other new mothers, or from their partners (Darvill et al., 2010). Transition to motherhood can also be related to pain during the birth. By “being one’s body”, the woman has gone through the experience in a way that was meaningful for her in new life situation with her new baby (Lundgren & Dahlberg, 1998).

The transition is a result of change during the life, e.g. pregnancy and childbirth. Midwives have an important role during the transition, to support and to acknowledge the women. However, to do it in the best possible way and with evidence, this requires knowledge about physiological changes, as well as the psychological processes during a pregnancy. Midwives and obstetricians have to be aware of the impact that a positive transition has on women.

3 RATIONALE

In Sweden, about 15-20% of pregnant women have a late term pregnancy, (41+0 gestational weeks), and about 5-7% of women have a postterm pregnancy, (42+0 gestational weeks) (Socialstyrelsen, 2015). To date, the policy of management for pregnancies ≥41+0 gestational weeks is to induce labour at 42+0 gestational weeks. Globally there exists no uniform policy for managing late term pregnancies (≥41 gestational weeks). In particular, there is no scientific evidence for induction of labour at 41+0 gestational weeks or induction of labour at 42+0 gestational weeks, regarding neonatal and maternal outcomes. The WHO suggest early induction at 41+0 gestational weeks (WHO, 2018b). However, published international guidelines suggest induction at 41+0 – 42+0 GW gestational weeks (ACOG, 2014; NICE, 2014)

When the SWEPIS trial and the doctoral project were planned, the previously published studies comparing induction at 41+0 versus 42+0 gestational weeks suffered from small numbers of participants or lack robust methodology. In some of the larger trials, healthy women with normal pregnancies had been mixed with pregnant women with medical diagnoses. The question of the correct time for induction is still under debate worldwide and so is the policy regarding correct management. The current general trend, however, is towards induction earlier than 42+0 gestational weeks, although it is not clear what the effects are on maternal and foetal morbidity and mortality.

Previous research has mainly been focused on medical issues, e.g. different induction methods, when to intervene, maternal risk factors, risk for late and postterm pregnancy, and on foetal and maternal morbidity and mortality. However, there has been little research done on women's experiences of a pregnancy at ≥41 gestational weeks, and regarding what type of support this group of pregnant women need.

This thesis includes the planning and execution of a register based randomised controlled trial as well as assessment of women's experiences through performing two qualitative studies utilising phenomenological and lifeworld hermeneutic theoretical approaches. The purpose is to increase knowledge about the management of pregnancy and deepen the knowledge about women's experiences of a pregnancy ≥41 gestational weeks, as described during pregnancy and after birth. The results can be used to develop better clinical guidelines according to the best available evidence and will bring new knowledge for midwives, obstetricians and other health care professionals in the management of late term pregnancy.

4 AIM

The overall aims of the present thesis were:

1. To investigate if a policy of induction of labour at 41 gestational weeks is superior, in terms of neonatal and maternal outcomes, as compared to expectant management and induction at 42+0 gestational weeks, among healthy women with a low risk/uncomplicated singleton pregnancy (SWEPIS study).

2. To gain a deeper knowledge about women's experiences of pregnancy ≥41 gestational weeks, as described during pregnancy and after birth.

Specific aims were:

Study I: To design a study to evaluate if a policy of induction of labour at 41+0 gestational weeks (early induction) is superior, in terms of neonatal and maternal outcomes, as compared to expectant management and induction at 42+0 gestational weeks (late induction) in healthy women with a low risk singleton pregnancy.

Study II: To evaluate if the induction of labour at 41+0–2 weeks compared with expectant management (induction of labour at 42+0–1 weeks), is superior in terms of perinatal outcome in healthy women with a low risk pregnancy (SWEPIS study).

Study III: To describe pregnant women's lived experiences of a pregnancy ≥41 gestational weeks with a phenomenological approach.

Study IV: To describe women's experiences of a pregnancy ≥41 gestational weeks after childbirth with a lifeworld hermeneutic approach.

5 METHODS

New scientific knowledge can be acquired using different research methods and quantitative and qualitative methods can be combined to complement each other. Both quantitative and qualitative research methods were used in the current thesis. Study I included the planning, writing, and publication of the study protocol for the multi-centre, registry-based randomised clinical trial (R-RCT) in Study II. Study II entailed execution of the study, including randomisation and treatment of two intervention groups, data collection, and statistical analyses. Studies III and IV were qualitative studies, conducted with interviews. The analysis was done with a phenomenology approach in Study III and with a lifeworld, hermeneutics approach in Study IV. Both the phenomenological and the lifeworld hermeneutic approaches in this thesis have their ground in lifeworld theory (Dahlberg, Dahlberg, & Nyström, 2008).

5.1. Research design

Table 4. An overview of the studies included in this thesis

Study	Design	Data collection	Participants (n)	Data analysis
I	Study protocol	Not applicable	Not applicable	Not applicable
II	Registry-based multicentre randomised controlled trial (R-RCT)	Data from The Swedish pregnancy register and The Swedish Neonatal Quality Register	2760	Non-parametric statistical tests
III	Interview study	Individual interviews	10	Phenomenology
IV	Interview study	Individual interviews	10	Lifeworld hermeneutics

5.1.1. Statistical analyses

The statistical analyses were done on the outcomes in the Intention to Treat (ITT) and Per Protocol (PP) populations. The ITT population consisted of all the randomised women who did not withdraw their consent (Gupta, 2011). The PP population was smaller and consisted solely of the randomised women who received allocated intervention in their respective group, or who proceeded to spontaneous labour. Dropouts from the study (i.e., not included in the PP population, but who were included in the ITT population) were due to unexpected medical conditions that occurred after randomisation, induction of labour before 41+0 gestational weeks, or practical matters in the hospital such as lack of space in the labour ward. The analysis methods that were used for the different types of outcomes are presented in Table 5. Risk ratios (RR) and risk differences were calculated, with 95% confidence intervals and significance levels at $p<0.05$.

Table 5. Statistical analysis methods used in Study II.

Two-sided Fisher's exact test	Comparing the primary perinatal composite outcomes between the two groups
Fisher's exact test	Comparing the secondary outcomes, for dichotomous variables
Fisher's non-parametric permutation test	Comparing continuous variables
Mantel Haenszel chi-square test	Comparing ordered categorical variables
Pearson's chi-square test	Comparing non-ordered categorical variables

5.1.2. Phenomenology and lifeworld hermeneutics

The philosopher E. Husserl (1859-1938) is seen as the father of (modern) phenomenology. Further, Husserl and Merleau-Ponty (1908-1961) have been important for the development of phenomenology and lifeworld theory (Dahlberg et al., 2008). Within phenomenology, the central concept is the phenomenon, meaning an object as experienced by a subject. In these studies,

the studied phenomenon is late term pregnancy as experienced by women during pregnancy and after birth (Study III and IV). The aim is to "go to the things themselves", that is, something as it is experienced by somebody (Dahlberg et al., 2008). The researcher needs to be open, adherent, and sensitive to the experience, to get hold of things as they turn out, how they show (Dahlberg et al., 2008). Husserl originally described the lifeworld approach, which was further developed by Merleau-Ponty, and led to the established lifeworld theory (see below) (Dahlberg et al., 2008). The lifeworld approach can be expressed as "being to the world". Hermeneutics is a philosophy of understanding with a long tradition, which consists of different approaches and perspectives. Friedrich Schleiermacher (1768-1834) introduced hermeneutics as a method for interpretation. Heidegger (1889-1976) developed this from a methodology to an existential philosophy. Heidegger said that we always have the old experiences with us when we meet something new, and that interpretation is something fundamental for human beings (Dahlberg et al., 2008). In the current thesis, lifeworld hermeneutics was used in Study IV, which is grounded in lifeworld theory (Dahlberg et al., 2008).

Our lifeworld is the world where the humans live their lives. How humans interact and relate to the world shows how we are to the world. The past, the present, and the future are involved in the lifeworld theory (Dahlberg et al., 2008).

In research with the lifeworld approach, openness is central. The researcher needs to be interested in how phenomena present, without prepared questions about such phenomena (Dahlberg et al., 2008; Thomson, Dykes, & Downe, 2011). It is important to be open to what the interviewee says during the interview and to what this shows in text during the analysis phase. To be open also means that you have to be aware and bridle your own preunderstanding during the interview and when analysing the text. To bridle the preunderstanding means that the researcher strives for an awareness of their own preunderstanding and tries not to influence the process and the results. It is important to bridle preunderstanding to be able to see the results with as little impact as possible from the researchers' personal views and from earlier knowledge regarding the specific topic. To see unconditionally with a reflective attitude requires an open mind from the researcher (Dahlberg et al., 2008; Smith, 2007).

In both phenomenology and lifeworld hermeneutics, a methodological assumption is to understand the whole from the parts and the parts from the whole. There is a movement during the analysis, back and forth between the

whole (the transcribed text from the interview) and the parts (the analysis), and back to the new whole (Dahlberg et al., 2008). Gadamer named this movement the "hermeneutic circle" (Gadamer, Marshall, & Weinsheimer, 2004). In lifeworld hermeneutics the main interpretation is based on the themes that have emerged, and the interpretation can use a metaphor, concept, or theory to achieve a deeper understanding (Dahlberg et al., 2008). In phenomenology, the new whole is the essence, which should consist of variations in the data. The essence is on a higher level and describes the variation in the phenomenon by its constituents. In lifeworld hermeneutics, the new whole is the main interpretation. The main interpretation covers different themes and gives a comprehensive understanding, which makes it possible to more easily understand the result (Dahlberg et al., 2008).

Phenomenology and lifeworld hermeneutics are similar in the first phase of the analysis phase. Both methods start with marking meaning units in the text, which are parts corresponding to the studied phenomena. In phenomenology, the meaning units are then put together in clusters, but these clusters are not reported in the findings. In lifeworld hermeneutics, the next phase is instead the extraction of sub-themes and themes. The results are thus presented in different ways in these two approaches. In phenomenology, you present the result as the essence and the constituents. The constituents describe the essence and the variation in the phenomenon. In lifeworld hermeneutics, the themes form the underlying base for the main interpretation (Dahlberg et al., 2008).

5.2. Data collection

5.2.1. Study I

Study I was the study protocol for Study II, which was published prior to the start of the trial. The purpose of publishing a study protocol is to ensure that data collection and analyses of the primary and secondary variables in the main trial are done according to the original plan.

A steering committee was responsible for the design of the study and writing study protocol. It consisted of senior representatives from the clinical and university staff, and researchers from the obstetrician and midwifery professions. The committee managed contact and coordination between the participating centres, and was responsible for monitoring and ensuring the progress of the study, data collection and analysis, and for compiling results and writing manuscripts. The committee also managed information and

logistics at the participating centre at the Sahlgrenska University Hospital, including and randomisation of the participating women.

A Data Safety Monitoring Board (DSMB) was also created before the start of the trial. This was an external group with competence in relevant areas, whose purpose was to verify that the trial was being run safely and in accordance with the study protocol and the ethical statements. The DSMB for the current study consisted of one senior obstetrician, one senior midwife, and one statistician.

5.2.2. Study II

Study II, the SWEPIS study, a registry-based, multicentre randomised controlled trial, was conducted from May 2016 until October 2018.

5.2.2.1. Study population

Inclusion criteria were:

- Healthy women without major medical illness.
- Age ≥18 years.
- Single viable pregnancy with cephalic presentation of the foetus.
- Gestational age at randomization from 40+6 to 41+1 gestational weeks, based on the estimated due date from an ultrasound examination before 22+5 gestational weeks.
- The participating woman should be capable of reading and understanding written and oral information.
- The women should be willing to participate in the study and sign an informed consent form.
- The pregnancy should be allowed to reach 42+0 gestational weeks without any existing medical or other concerns.

Exclusion criteria were:

- Hypertensive disorders or pre-eclampsia.
- Pre-gestational and insulin dependent gestational diabetes.
- Previous caesarean section or other uterine surgery.
- Small for gestational age foetus (SGA) (<22% according to the sex specific Swedish reference).
- Oligohydramnios (amniotic fluid index <50 mm or deepest vertical pocket <20 mm).
- Diagnosed foetal malformation.
- Multiple pregnancy.
- Women with premature rupture of membranes.
- Breech or transverse position of the foetus.

- Contraindications for vaginal delivery: placenta praevia, accreta, vasa praevia.
- Women where signs of labour had already started, with cervical change and regular contractions.
- Women who previously participated in the study.

5.2.2.2. Data collection and randomisation

At around 40 gestational weeks, the women fulfilling the inclusion criteria were given both oral and written information about the study from their responsible midwife at their antenatal care unit. There was also a website for the study, and posters displayed in the waiting room. The randomisation period was from 40+6 to 41+1 gestational weeks. At the hospitals in the Stockholm region, there was a voluntary ultrasound at 41 gestational weeks for screening for intrauterine growth restriction (IUGR) and for oligohydramniosis. The patient information was translated into 17 different languages: English, Spanish, Somali, Persian, Arabic, Croatian, Sorani, Thai, Tigrinya, Russian, Mongolian, Farsi, Serbian, Albanian, French, Polish, Turkish, and Dari.

The patient information and the informed consent form used were the same at all the participating centres. The ethical committee in Gothenburg approved the patient information and the informed consent form before the start of Study II.

Women who were eligible and willing to participate in the study, and willing to sign the informed consent form, were randomised at participating antenatal care units after receiving more information. At some of the participating hospitals, there were study midwives who gave additional information, booked the women for randomisation if they were still interested in participating, and then did the randomisation. In the Gothenburg region at Sahlgrenska University hospital, the women who were interested in participating called the doctoral student midwife or midwives working in the project to receive more information by phone and for booking a meeting for randomisation. In the Stockholm region, the women got the information from the midwife at the antenatal unit, and they were randomised at the ultrasound clinics after the examination and assessment that the pregnancy could proceed to 42+0 gestational weeks.

Study II was a registry-based randomised clinical trial (R-RCT). This means that, while it was a controlled randomised trial, a clinical registry was used for randomisation, for collection of baseline data and outcomes from the women's electronic records (James, Rao, & Granger, 2015; Li et al., 2016). Block randomisation within the Swedish pregnancy registry with a fixed block size (unknown to the investigators) was done online, 1:1, using a module specifically developed for the study by MedSciNet AB (Stockholm, Sweden). The block was per participating centre and group. Furthermore, the Swedish

Neonatal Quality Register (SNQ) was used for collection of neonatal data, and the electronic Case Report Form (eCRF) was used for complementary maternal information. From these three registers, data was obtained about the pregnancy and delivery outcomes, maternal backgrounds, and outcomes for the neonatal variables.

In total, 14 hospitals were involved in the study, five university clinics, and nine county hospitals. The study started at Sahlgrenska University Hospital in Gothenburg in May 2016. From January 2017 to December 2017, 13 more hospitals decided to participate. Participating hospitals were Sahlgrenska University Hospital, Uppsala University Hospital, Falun Hospital, South Älvsborg Hospital in Borås, Södertälje Hospital, Karolinska Solna, Karolinska Huddinge, Danderyd Hospital, South BB at South Hospital in Stockholm, Örebro University Hospital, Halland Hospital Varberg, Halland Hospital Halmstad, Visby Hospital, and North Älvsborg Hospital (Trollhättan/Vänersborg/Uddevalla).

In the hospitals in Gothenburg, Örebro, and Falun, the women also answered a questionnaire at the same time as the randomisation. The questionnaire consisted of baseline data and reliable and validated measurements: The Euro-Qol-5 Dimension scale (EQ-5D), the Euro-Qol-Visual Analogue Scale (EQ-VAS) (Rabin & de Charro, 2001), Big Five (John & Srivastava, 1999;2), the General Self-efficacy Scale (GES) (Koskinen-Hagman, Schwarzer, & Jerusalem, 1999), and the Pain Catastrophizing Scale (PCS) (Sullivan, 1995). The women answered the questionnaire on a touchpad computer. The women also answered a questionnaire three months after labour, which consisted of the EQ-5D, the EQ-VAS, the GES, the PCS, and the Childbirth Experience Questionnaire (CEQ 2.0) (Dencker, Taft, Bergqvist, Lilja, & Berg, 2010). The results from the questionnaires will be presented in upcoming scientific publications and are not part of the present thesis. There is also a planned four year of follow-up of the children, and a planned health economics analysis.

5.2.2.3. Primary outcomes

In Sweden, the rate of stillbirth during the last decade has been around 3-4 ‰ (Socialstyrelsen, 2015, 2018). The power analysis showed that 10.036 pregnant women (5018 in each group) should be included to achieve statistical significance of a reduction in the primary outcome by one third from 2.74 to 1.84%. The power analysis was calculated on the rates of perinatal mortality and morbidity during 2000 – 2010 in gestational weeks 41+3 in one Swedish region (Region Skåne). The power analysis was based on 30% participation by the women who were eligible to participate in the study. Due to the low rate of stillbirth in Sweden, the steering committee chose a composite adverse perinatal outcome that combined perinatal mortality and morbidity. This perinatal death measure included stillbirth and neonatal death 0-27 days after

the birth. Neonatal morbidity was defined as at least one of the following outcomes:

- Apgar score less than 5 at five minutes.
- pH less than 7.00 or metabolic acidosis (pH <7.05 and base deficit <12 mmol/l in the umbilical artery).
- Intracranial haemorrhage.
- Hypoxic ischemic encephalopathy I-III.
- Meconium aspiration syndrome.
- Convulsions.
- Obstetric brachial plexus injury.
- The newborn requiring mechanical ventilation for more than 72 hours.

5.2.2.4. Secondary outcomes

The neonatal secondary outcomes were:

- Apgar score less than 4 at five minutes
- Macrosomia (weight at birth equal to or more than 4.5 kg)
- Requiring admittance to neonatal intensive care unit.
- Neonatal jaundice.
- Therapeutic hypothermia.
- Sepsis.
- Pneumonia.
- Birth trauma.

Secondary maternal outcomes were:

- An acute caesarean section.
- Vaginal delivery requiring surgical intervention.
- Use of epidural anaesthetic.
- The duration of labour, in hours.
- Shoulder dystocia.
- Chorioamnionitis.
- Perineal tear of degree III-IV.
- Cervical laceration.
- Post-partum haemorrhage >1000 ml.
- Uterine rupture.
- Retained placenta.
- Preeclampsia or hypertension.
- Post-partum infection (wound infection), endometritis, urinary tract infection, or sepsis.
- Admission to an intensive care unit.
- Venous thromboembolism.

- Depression and/or anxiety, diagnosed during the stay in the hospital.
- Duration of stay in hospital, in hours.
- Breastfeeding at discharge from the hospital and four weeks post-partum.

5.2.3. Study III

The interview studies were performed before the start of Study II (SWEPIS). During the period from August 2013 to September 2014, participating women were recruited from one antenatal care unit in the Gothenburg city centre and two antenatal units in the suburban area of Gothenburg, Sweden.

5.2.3.1. Study population

The inclusion criteria were a healthy pregnant woman, without any systemic diseases, ≥18 years old. The pregnancy was expected to be normal and at recruitment to the study, the pregnancy was at gestational week 41+0 – 41+6. The women should speak Swedish.

5.2.3.2. Data collection

During an appointment for regular check-up at their antenatal care unit at around 40 weeks, the woman got oral and written information about the study from their midwife. A time for the interview was booked by phone by AW. The women chose the location for the interview since it was important that the woman should feel comfortable and relaxed during the interview. AW conducted the interviews in the women's home, at the university, or at the antenatal care unit.

At the interview, the woman first received both written and oral information about the aim of the study, and confidentiality of the data. They also got information about the voluntary nature of participation and that they could withdraw their agreement of participation whenever they wanted. The woman then signed an informed consent form. All the women also got information about the second interview that was planned to be conducted two to three months after birth.

The interviews lasted 25–55 minutes and were digitally recorded on a small portable audio recorder. The initial open question was "Can you tell me about your experiences of 41 completed gestational weeks?" This was followed by follow-up questions to gain a deeper understanding, for example, "Can you tell more about… ?", or "Can you describe more about… ?". All the interviews were transcribed verbatim. All the women got information that they could

receive further support if they felt that they had a need, but this was not requested by any of the participants.

5.2.4. Study IV

Study IV was conducted from October 2013 to November 2014.

5.2.4.1. Study population

The same ten women who were interviewed during pregnancy in Study III participated in the second interview. The inclusion criteria were the same as in the former study.

5.2.4.2. Data collection

The women called the interviewer (AW) for the second interview. The women received information about the purpose of the study, and that the participation was voluntary. AW booked the day and time for the second interview by phone. As for the first interview, the women chose the place for the interview themselves. They did not sign a second informed consent form at the second interview, since the first informed consent also applied for the second interview.

The interview started with an open question "Can you tell me about your experiences of a pregnancy that lasted more than 41 gestational weeks?". To gain a deeper understanding, follow-up questions were asked, such as "Can you describe more about…. ?". The interviews were recorded digitally, lasted 35–55 minutes, and were transcribed verbatim. All interviews were conducted two to seven months post-partum.

All women were offered a follow-up meeting, but this was not requested by any of the participants.

5.3. Data analysis

5.3.1. Study I

Not applicable.

5.3.2. Study II

The main analysis was to compare the early induction group versus the expectant management group in the ITT and PP populations. Different statistical methods were used to analyse the outcomes. Non-parametric

statistical tests were used, since it was not assumed that data were normally distributed. For the variable "primary composite perinatal outcome" and for all dichotomous variables, Fisher's exact test was used. For continuous variables, Fisher's non-parametric permutation test was used. For ordered categorical variables, the Mantel-Haenszel chi-square test was used, and for non-ordered categorical variables Pearson's chi-square test. 95% confidence intervals (CI) and risk ratios were calculated for analyses comparing the two groups and for estimated proportions. Significance tests were conducted at $p<0.05$ significance levels and were two-sided (see Table 5).

5.3.3. Study III

The phenomenological reflective lifeworld approach (Dahlberg et al., 2008) was the ground for the analysis. All the interviews were digitally recorded and transcribed verbatim. All the texts were then read and re-read several times to get a sense of the data and the completeness. The next step was to identify meaning units which corresponded with the aim of the study. Throughout the analysis a movement between the part and the whole was done in order to not miss any important information from the data. The next step was to group the meaning units into different clusters; however, the clusters are not described as a result, but as one dimension and part of the analysis phase. The clusters then formed the base for describing the essence with the constituents, the different parts with all variations and nuances in the essence.

5.3.4. Study IV

The lifeworld hermeneutic approach was used for the analysis (Dahlberg et al., 2008). The first step in the analysis process was to read the transcribed interviews. The texts were read and re-read several times to get a sense of the whole data with the aim for the study in focus. The next step was to identify meaning units that correlated with the aim of the study. The meaning units were then grouped based on similarities and preliminary themes were formulated. The next step was to read the meaning units and preliminary themes again, with the aim of formulating a main interpretation. For this analysis Pia Olsson's metaphor "nocturnal voyage in unknown waters" (Olsson, 2000) was used. The themes were then related to the metaphor before being finalised. Finally, the themes and the main interpretation based on the metaphor were presented.

6 RESULTS

Results of the outcomes in SWEPIS and results from the qualitative studies, Study III and IV are presented in this chapter.

6.1. Study I

Not applicable.

6.2. Study II

The DSMB group received data once per semester from the ongoing trial and performed preliminary analyses without informing the steering committee about the results. One task for the DSMB group was to give advice about whether the trial could proceed or had to be stopped, depending on the analyses of preliminary data. Thus, the DSMB advised to stop the study in October 2018 since the preliminary statistical analyses showed a statistically significant difference between the early and the late induction group in perinatal mortality. There were no perinatal deaths in the early induction group and at that point there were six perinatal deaths in the late induction group, broken down as five stillbirths and one early neonatal death (p=0.031). Due to this result, on October 13, 2018 the study was temporarily stopped after recommendation by the DSMB. The steering committee for the study decided to finally stop the study on December 21, 2018 after all the data on neonatal mortality (death 0–27 days) and composite primary neonatal outcome had been validated.

Study II was conducted from May 2016 to October 13, 2018. Informed consent was signed by 2762 women, who were randomised either to induction at 41 gestational weeks and 0-2 days (early induction group), or to expectant management or induction at 42 gestational weeks and 0-1 days (expectant management group). Two of the women in the early induction group changed their mind and withdrew their informed consent to participate in the study. This was done after the randomisation, but before induction.

The early induction group consisted of 1381 women and there were 1379 women in the expectant management group. In the expectant management group, local guidelines for check-ups were used, and induction of labour was done at 42 gestational weeks plus 0-1 days if labour not had started spontaneously.

In the early induction group, there were no adverse perinatal outcomes, but in the expectant management group there were five stillbirths and one neonatal death (0-27 days) (p=0.031). In one of the cases of stillbirth, the autopsy and post mortem examination showed cardiovascular malformation with a totally anomalous pulmonary venous return/drainage (TAPVR/TAPVD), and the placenta showed signs of chorioamnionitis. However, specialists in child cardiology assessed the results from the post mortem examination and concluded that the effect of the malformation was not lethal by itself. There was no obvious explanation for the other four stillbirths. The neonatal death was a newborn who died four days after birth due to hypoxic-ischaemic encephalopathy (HIE) associated with multiple organ failure.

There was no difference in the composite primary outcome (see the primary outcomes in section 5.2 and Results in Study II) between the early induction group (2.4%, n=1381) and expectant management group (2.3%, n=1379; p=0.90). Further, there was no difference in caesarean section rate or other perinatal outcomes between the groups.

There was no difference in baseline characteristics such as age, parity, and body mass index (BMI) between the early induction group and the expectant management group. There was no difference in number of women with a spontaneous start of labour between the two groups (see Study II).

In the secondary outcomes for the neonates, the result showed a significant difference between the two groups with an advantage for the children born in the early induction group. There was a higher rate of neonates who were admitted to an intensive care unit in the expectant management group (n=55/1381 (4.0%) vs. n=82/1379 (5.9%), p=0.022), and a higher rate of neonatal jaundice (n=16/1381 (1.2%) vs. n=32/1379 (2.3%), p=0.028). More of the newborns were small for their gestational age in the expectant management group (n=22/1379 (1.6%) vs. n=9/1381 (0.7%), p=0.028), and more newborns were also large for gestational age in the expectant group (n=114/1379; 8.3%) vs. the induction group (n=68/1381 (4.9%), p=0.0005).

In the secondary maternal outcomes, more women in the early induction group suffered from endometritis, compared to the expectant management group (n=18/1381(1.3%) vs. n=6/1379 (0.4%), p=0.022).

6.3. Study III

This study was conducted from August 2013 to September 2014 at one antenatal unit in the central part and two units in the Gothenburg suburban area. Ten women participated in the study; they varied in age between 23 to 37 years (mean 30.5). All women were cohabitating or married. Seven women had a university degree and three had a primary and secondary school degree. Two women were expecting their second child and eight women their first child. Swedish was the first language for all of the women.

The results showed that the essence was that the women were in a state of limbo, a void characterised by contradiction in relation to time, giving birth, and the condition and treatment from the caregivers. Five constituents emerged from the essence: the first constituent was negative feelings and thoughts; second, difficulty associated with waiting for labour; third, unmet expectations; fourth, seeking alternative sources of information; and fifth, the influence of others.

The conclusion is that the women experienced a time that should not exist; they felt that they were in limbo. The women had not expected this time of waiting. This time of limbo was a time, which included contradictory feelings about time, about the body's ability to give birth, the lack of information from the midwives, and not being seen by the caregivers. These feelings tended to become more negative as the pregnancy progressed.

6.4. Study IV

This study was conducted from October 2013 to November 2014. In this study the same women participated as in Study III. The study was conducted at one antenatal unit in Gothenburg and at two antenatal units in a suburb of Gothenburg.

The main interpretation was based on Olsson's metaphor "a nocturnal voyage in unknown waters" (Olsson, 2000). From the data analysis, six themes emerged and got their final theme names after the interpretation: the first theme was doubting the body's ability to cope with the transition from pregnancy to giving birth; second, the importance of their partner's support during the sea voyage; third, the lack of clear guidelines for the voyage; fourth, worrying about the cargo at the end of the voyage; fifth, how the voyage turned out; and last and sixth, thoughts related to a future voyage.

The main interpretation was that the women experienced the time of waiting for the labour as the start of a voyage into unknown waters: the pregnancy as the voyage, the women as the captain, the partners as the first mate, the unborn child as the cargo, the midwife as the main inspector, and the upcoming birth the harbour. The women were out sailing in unknown waters without any sea charts. She struggled to find the right way without hitting any cliffs and rocks. She was also anxious for the unborn child, the cargo, and what could happen. She also started to think about the upcoming birth. The captains wished that the ship would be able to enter the harbour by itself, without help from other people.

The conclusion is that the women did not feel empowered enough at the end of their pregnancy. They doubted their bodies' own ability to give birth and the transition from pregnancy to birth.

7 ETHICAL CONSIDERATIONS

The studies in this thesis were designed in conformity with ethical principles and guidelines of the World Medical Association Declaration of Helsinki ("World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects," 2013). This declaration was created to make sure that certain ethical principles were met when human subjects are involved in research. These ethical principles are that all human subjects should be treated with respect for the individual, which can be a human with either full or diminished autonomy, and that their rights and health should be protected. The researcher must have assessed the risks in the research project, and the project must be monitored and documented. One overreaching principle is to do no harm. An ethical basic principle is that all participation in a research project should be voluntary. The person involved in a project can withdraw the informed consent at any point, without having to reveal the reason for this to the research leader or someone else in the research group.

The General Data Protection Regulation (GDPR) is a legal framework that establishes guidelines for the collection and processing of personal data by persons residing in the European Union (EU). GDPR started on May 26, 2018 and replaced the earlier European Data Protection Directive. At the start of the present study, the relevant legal framework was the Swedish Patient Data Acts (PDA) (SFS 1998:2 004). The studies were planned according to these regulations regarding the personal integrity for the included women, their names and national identification numbers, and for management, collection, and storage of data.

Pregnant women are in a special life-changing phase in their life and for some women this is a vulnerable period in their life. During a pregnancy, a woman's body undergoes physiological changes that can affect her mental state and contribute to a sense of vulnerability. Thus, to get the question of whether to participate in a study where you can be randomised for induction at 41 gestational weeks, which is not the standard procedure in Sweden right now, can be a dilemma for the woman.

The women in Study II got both oral and written information about the study, first from the responsible midwife at the antenatal unit, and then additional information during a telephone conversation when booking the appointment for the randomisation (Gothenburg region), and more if needed before the randomization and signing of the informed consent. Some women who might have needed an interpreter during the information may have missed the aim of the study and therefore choose not to participate. In the patient information that the women received, the confidentiality of the study was clearly stated, including the fact that no unauthorised person would have access to the results, and that the data would be stored for 10 years. Their national identification

number and name were replaced with an ID number, which could not be tracked back to the participant as an individual. Furthermore, it was clearly stated that they could withdraw their participation whenever they wanted, without telling anyone the reason.

For Study II, the ethical approval was obtained from the regional ethics committee in April 2014 (number 285-14). The RCT study was registered in Current Controlled Trials, ISRCTN26113652 in March 2015 (DOI10.1186/ISRCTN26113652 and complementary amendments (T 905-15, T 291-16, T 1180-16, T 330-17, T 347-18, T 961-18, and T 1110-18).

The steering committee was responsible for managing the progress of the trial. The Data Safety Monitoring Board's (DSMB) responsibility was to monitor the progress of the trial, to review it periodically, to ensure the safety for the persons included in the trial, to give advice about the continuation of the ongoing trial, and if needed, to provide advice for modification and termination of the trial (Holubkov et al., 2013).

In Study II the women who came for the randomisation got extra time for information from a midwife. The women and partner got additional information about the study, but also about the induction and the different induction methods. The women expressed that they were grateful to receive this extra time with the midwife.

In Study III, the women were grateful for the extra information and the talk with information that they had after the interviews were conducted. They expressed that they got more information about induction methods, the stay at the hospital, and about breastfeeding in some cases. They felt relieved after the information.

The ethical considerations for the two interview studies, Studies III and IV, were described in the patient information. The purpose of the study was stated, that is was voluntary to participate in the study, that participation could be withdrawn at any point without informing the interviewer or anyone in the research team about the reason, and that this would not affect their ongoing care.

For the interview studies, the ethical approval was obtained from the regional ethics committee in May 2013 (number 313-13).

8 DISCUSSION

The results from Study II showed a significant difference in the perinatal mortality rate between the early induction and expectant management and late induction groups. There were no significant differences in the primary composite adverse perinatal outcomes. Neither were there any significant differences between the two randomised groups in caesarean section or instrumental vaginal birth rates.

The results from the two qualitative studies in the present thesis show that the women were in a state of limbo, a void characterised by contradiction in relation to time, giving birth, and the condition and treatment from the caregivers. Further, the women experienced the time of waiting for the labour as the start of a voyage into unknown waters. The women expressed that they were not empowered enough at the end of the pregnancy, and they doubted their ability to give birth. Regarding a future pregnancy, they believed that they might have another postterm pregnancy, and they expressed a feeling that they would consider before deciding to get pregnant again.

The results in Study II corroborated previous research. Previous research with meta analyses, randomised controlled trials, and register-based studies, have also shown an advantage of induction earlier than 42 gestational weeks, with a lower rate in perinatal mortality (Gulmezoglu et al., 2012; Keulen et al., 2019; Middleton et al., 2018; Wennerholm et al., 2009; Zizzo et al., 2017). A recent review and meta-synthesis found that the risk for stillbirth was higher among pregnancies at 41 gestational weeks compared to 40 gestational weeks and even higher at 42 weeks of gestation (Muglu et al., 2019). Further, Study II did not corroborate the results from a systematic review from 2019, which showed increased risk for caesarean section, but which did not have statistical power to assess perinatal death (Rydahl et al., 2019).

The results from the Study II support early induction at 41 gestational weeks, as there was no increased rate of instrumental vaginal deliveries, caesarean section, or maternal morbidity. There were no differences between the early induction and expectant management group in the primary perinatal outcomes except the perinatal mortality. In summary, the accumulated knowledge about management of pregnancies lasting ≥41 gestational weeks shows an advantage of active management and early induction at 41 gestational weeks. It must be taken into consideration when assessing and discussing the result that the perinatal mortality is a rare event and that the other primary perinatal outcomes in Study II did not show any significant difference between the two groups. In any case, perinatal mortality is a very severe outcome. The result from Study II can be addressed in relation to one of the ICM's objectives, which is "Pregnancy and childbearing is a profound experience, which carries

significant meaning to the woman, her family, and the community" (ICM, 2014). A significant meaning for the women and the partner: they want a healthy child. If the result from Study II might lead to a decreased rate of perinatal mortality, this will make a definitive difference for families.

One thing to consider is the actual small difference between the two groups from randomization until birth, on average merely 2.9 days. All the perinatal mortality in the expectant management group occurred between 41+2 and 41+6 gestational weeks. None of the cases were from the Stockholm region, where an extra ultrasound is offered at 41+0 gestational weeks. However, it has not been shown that an extra ultrasound will decrease perinatal mortality or morbidity for a late term pregnancy (ACOG, 2014; Delaney & Roggensack, 2008; Nabhan & Abdelmoula, 2009).

Midwives in Sweden are responsible for a normal labour, birth, and post-partum care. A pregnancy is considered normal up to gestational weeks 41+6 and the policy for induction today in Sweden is induction at 42+0 gestational weeks. One of the ICM's philosophical objectives says "Pregnancy and childbearing are usually normal physiological processes" (ICM, 2014) and midwives have knowledge about the normal physiological processes, but also knowledge about and experience of medical complications during pregnancy and birth. Study II was stopped earlier than planned after the ethical implications of continuing the trial. As a midwife, obstetrician, or other health care professional, you always want the best for the women in front of you. This ties into one of the other philosophical objectives, "Pregnancy and childbearing is a profound experience which carries significant meaning to the woman, her family, and the community" (ICM, 2014). For the women, the transition from pregnancy to become a mother is one of the most important transitions during a woman's life (Nelson, 2002). The pregnant women and the partner want a living child, and given the result from the Study II and the INDEX study, a recently published study from the Netherlands, (Keulen et al., 2019), it might be hard to resist not to induce before 42 gestational weeks. However, it is important to investigate also women's childbirth experiences of induction at 41 gestational weeks and 42 gestational weeks respectively. The result from Study II may affect many women and statistically, the results mean that 250 women need to be treated (NNT) with early induction to prevent one infant death. Further, questionnaire studies on the women's experiences, and a national cost analysis have been done concurrently within Study II, and this will be presented in other scientific publications and theses.

The WHO has formulated a long-term goal to reduce maternal and neonatal mortality and morbidity, including stillbirth, with the statement "Every pregnant woman and new-born receives high-quality care throughout

pregnancy, childbirth and the postnatal period" (WHO, 2016) . In Sweden, the immediate results from Study II may be a change of the clinical guidelines to recommend induction of labour no later than at 41+0 gestational weeks. There is also a possibility to routinely offer an extra ultrasound at late term pregnancy, as is currently done only in the Stockholm region even though we do not know whether that would prevent perinatal mortality between 41 and 42 gestational weeks. In any case, it is important to provide clear information to women regarding the current state of knowledge regarding the correct management of late and postterm pregnancies, and to plan the woman's care in a discussion with her.

The results from the two qualitative studies in the present thesis emphasise the transition when the pregnant women start to doubt their own body's ability to give birth. According to ICM objectives "Midwifery care is emancipatory as it protects and enhances the health and social status of women, and builds women's self confidence in their ability to cope with childbirth" (ICM, 2014) and highlights the importance of the midwives work, which is to support pregnant women during the pregnancy.

The result from Study III showed that women experience that they are in limbo, a time that should not exist, that the midwife and other health professions did not see them, and that they were lacking information. The women started to mistrust their bodies' ability to cope with the birth. Even though they did not think that they should give birth at the estimated due day, they started to wonder if something was wrong with their body. One of the objectives from ICM, "Pregnancy and childbearing are usually normal physiological processes" (ICM, 2014) states the importance of the normality in the pregnancy and childbirth. The ICM objectives are in line with the review by Downe et al. (Downe, Finlayson, Tuncalp, & Metin Gulmezoglu, 2016), as is the result from the two qualitative studies in the current thesis. This review underscored the great importance of seeing the women and not only searching for pathology and treatments. Together with the physiology of the pregnancy and the upcoming labour, the women have needs that are emotional, cultural, and social throughout the pregnancy. Central factors in having a positive experience during pregnancy and birth are that women are seen and acknowledged, and that they get timely and appropriate information. Information was the one issue the women emphasised as lacking in Study III. The social environment today, with easy access to the internet, had an impact during the last week of pregnancy. A sense of lack of information was a reason to search the internet for answers that could have been provided by the midwife.

According to the women, it is clear that information and communication can sustain a woman's own inner strength to understand how her body is changing during pregnancy, and to provide trust in her own body's ability. The sense of a lack of information has been shown in earlier studies as well, and together with a lack of support from the midwives and other health care providers, women will experience their antenatal care as inadequate (Haines, Hildingsson, Pallant, & Rubertsson, 2013).

In Study III, the women expressed worries about the unborn child's birthweight, as they worried that the baby would be too big when the pregnancy had gone past more than 41 gestational weeks. One result in Study II was a significant risk in having a baby with macrosomia, which is in line with previous research (ACOG, 2014; Galal, Symonds, Murray, Petraglia, & Smith, 2012). Thus, midwives and other healthcare providers need to take into account that this concern can be relevant and to acknowledge women's worries during their encounters.

The result from Study IV is similar to Study III, but it also showed that the women were starting to think about a possible future pregnancy. The study showed their thoughts about a future pregnancy, and how the memory of the experience of the recent postterm pregnancy could have an impact on their future plans. They believed that they might have another postterm pregnancy, and they expressed a feeling that they would consider before deciding to get pregnant again.

The transition from pregnancy to motherhood with the birth of the first child includes social and physical changes, and acceptance of the change into the new phase in the life. The transition also has a wider connection with health, personal environment, and relationships (Bell, Erickson, & Carter, 2014; Meleis et al., 2000; Nelson, 2002). One of ICMs objectives is "Pregnancy and childbearing is a profound experience, which carries significant meaning to the woman, her family, and the community" (ICM, 2014) , which clarifies that the midwives' role during the pregnancy is to support the women, and empower them in such a way that it leads to a positive experience and a positive transition from the pregnancy to birth. Midwives mean to be with the women. Midwives are supposed to support the women during the pregnancy, birth, and post-natal care (Akuamoah-Boateng & Spencer, 2018; Berg et al., 2012). It clarifies the importance of the midwife to be with the women, and to see her as a person and not a medical or pathological issue, focused mostly on the estimated due date and not the woman's own experience. It is important to distinguish between what is normal and when something medical or pathological occurs, and there is a need to act accordingly.

Midwives and other care providers need to enhance women's confidence in their ability to cope with late term pregnancy and childbirth. A systematic review about postterm pregnancy and women's experiences and perceptions pointed to the impact of information. When women are informed about the management of their care, the benefits and risks, this strongly affects the choices she makes when she needs to make a decision. Different women have different needs, understanding, and philosophy regarding their care of with induction for postterm pregnancy. Therefore, to be able to provide individual support to the women, a women-centred care approach is recommended (Akuamoah-Boateng & Spencer, 2018). This can be emphasised when considering the results from Studies III and IV, where the women expressed that they were lacking information and individual support. When relating this to the results from the systematic review (Akuamoah-Boateng & Spencer, 2018) and to one of the objectives from ICM "Midwifery care is emancipatory as it protects and enhances the health and social status of women, and builds women's self confidence in their ability to cope" (ICM, 2014), it is clear that the women with a late term pregnancy need and should get more individualised care or women-centred care.

Healthcare professions and health systems need to make sure that all women receive evidence-based, equitable, high quality, and respectful care. The care needs to be given in a respectful manner, offered at the right time, and in a way that protects and promotes human rights (Miller et al., 2016).

9 METHODOLOGICAL CONSIDERATIONS

In the current thesis, both quantitative and qualitative methods were used. There were different aims in the different types of studies and the methods that were used reflect the different research questions. In quantitative research, to assess the level of evidence, criteria such as reliability, validity, and objectivity are used (Polit, 2018) Reliability and validity are measures that reflect how accurately a study is planned and conducted. While the **reliability** reflects the consistency of the study, validity is a measure of relevance, i.e. how much a sample really measures what it was aimed to measure. (Heale & Twycross, 2015; Polit, 2018). The **internal validity** is a criterion that is measured with as little bias as possible, whereas the **external validity** reflects if the result is generalisable to other settings (Heale & Twycross, 2015; Pannucci & Wilkins, 2010; Polit, 2018). Systematic errors can occur anywhere from the planning of the study until analysing the data, which includes the selection of the participants and the way the variables are documented and measured (e.g. if there are any confounding factors) (Pannucci & Wilkins, 2010). **Objectivity** is the way the results are accounted for without any bias(es) from the researcher (Polit, 2018). As the researcher and author, to achieve representative and generalisable results, it is important to be aware of these criteria during the process from the study design, implementation of the study, to analysing the data, and to minimise and avoid biases that can occur during the different steps in the process.

Trustworthiness in quantitative research can be described as level of confidence in the data and the analyses. The trustworthiness is assessed by five criteria, as defined by Lincoln and Guba (Lincoln & Guba, 1985): **credibility**, **transferability**, **confirmability**, **authenticity,** and **reflexivity**. These criteria are seen as comparable to reliability, objectivity, and validity in quantitative research (Polit, 2018).

9.1. Study I

The randomised controlled trial (RCT) is seen as the method that can provide the strongest evidence (James et al., 2015). The particular advantage with an RCT is that two balanced groups are compared: one intervention and one control group. The groups are pre-specified, as well as the outcomes, and the effect of randomisation is to reduce the biases (Hariton & Locascio, 2018). Study I is the protocol for Study II, which is a registry-based prospective randomised controlled trial. The registry is both a base for the randomisation

and for storage of data, which can strengthen the internal validity. The quality of the data in the registry relies on the way the data are registered. It is not always possible to blind the data in a randomised controlled trial (Li et al., 2016). In Study II, it was not possible to blind which group the women were randomised to, but during the analysis stage, the data were blinded to the statisticians with respect to group. The advantage of a registry-based trial is that data can be collected for many years, often since the registry was started, and the persons in the registry can be linked going back several years. In contrast, purely register-based research does not carry as strong evidence as an RCT, but can be seen as a complement or foundation for an RCT (Olsen, 2011).

Study I describes the aim for the study, inclusion and exclusion criteria, the implication of the trial, and the statistical methods to be used in Study II. Thus, the aim of the protocol was to minimise the eventual bias by clearly stating the research question, and the way the trial would be implemented and analysed. It is important to have a published study/analysis plan for the credibility of the result in randomised controlled trials (Gamble et al., 2017; Ioannidis, 2018).

There were extensive discussions in the steering committee, which would be responsible for the study regarding the inclusion criteria, for example regarding exactly what was meant by a healthy woman with a normal pregnancy. The plan was to include a population of women, which could reach 42+0 gestational weeks. Healthy women here included women with no existing medical issues that could affect either the woman or the foetus. The steering committee decided to exclude women with a previous caesarean section or who had undergone any other surgery on the uterus, due to the risk for a rupture of the uterus during birth. There was also a discussion about women with obesity, and it was decided to include them in the study since this would better reflect the true composition of the population. It is known that the risk for IUFD is higher among women with obesity (Stubert, Reister, Hartmann, & Janni, 2018).

9.2. Study II

9.2.1. Reliability

Reliability assesses the errors in the measurements, with the goal being as small an error as possible (Polit, 2018). Reliability in Study II was strengthened through having the aim and methods clearly stated in the published study protocol (Study I). For the statistical analyses, a statistical analysis plan (Gamble et al., 2017) was written, and signed by persons who were in charge

for the study. The database was closed before the start of the analysis of the data. After Study II was prematurely terminated all the results were validated by the research group, and externally by a group not involved in the project to find any errors in the data.

9.2.2. Internal validity

Internal validity defines to what degree the observed results are caused by the intervention (the independent variable) and not by cofounding factors (Polit, 2018).

Internal validity in Study II was strengthened through the following actions: randomisation was done through the Swedish pregnancy registry (Stephansson, Petersson, Bjork, Conner, & Wikstrom, 2017), which can be seen as a strength, in that the registry records data already from the first antenatal visit, through the childbearing period, the birth, and it also records data for the neonate. The pregnancy registry started in 2013, and during the planning and start-up of the study, not all of the participating centres were fully connected to the registry, which can be seen as a weakness. Relying on the registry can both be seen as a safety measure when handling and analysing the data, but on the other hand, errors in the data can result from mistakes that were made during documentation in the medical record systems. Most of the data in Study II were from the Swedish pregnancy registry (Stephansson et al., 2017) and the Swedish neonatal quality registry (SNQ) (Norman, Kallen, Wahlstrom, & Hakansson, 2019), but there were also some variables from the e-CRF (electronic Case Report Form) (Bellary et al., 2014). The e-CRF was a complement to the pregnancy registry and was documented manually by going back in the patient's records and then completing the e-CRF.

In Study II, block randomisation was used. This is used when the purpose is to have groups with an equal number of participants in each group, and the advantage is to increase the level of comparability of the outcomes (Lim & In, 2019; Suresh, 2011). In the design of the study, the women were randomised per participating centre, so that the number of primiparas and multiparas were similar in both the early induction and expectant management groups. This means that bias was minimised, and that results from each centre could be analysed separately, if required and of course with the limitation of statistical power.

9.2.2.1. Selection bias

According to the data in the registries, the number of healthy women with a normal pregnancy who could have been included in the study during the trial were n=19,079. Of the eligible patients, n=16,317 women declined to participate in the study or did not meet the inclusion criteria, or were never informed about the study.

Two women withdrew the informed consent before the intervention started. This meant the total number of included women in the ITT population was 2760. The final number of women in the early induction group was 1381. Of these, 1333 received the intervention and 48 women did not receive the intervention due to administrative errors, request by the woman, or lack of capacity at the wards. In the expectant management group, the final number of women was 1379, since 28 did not receive the intervention due to administrative errors or request by the woman.

Thus, the achieved participation rate was 14.5%. The lowest rate of participation was 3.6% at the North Älvsborg Hospital, and the highest rate was 49.2% at Visby Hospital. Study II started at Sahlgrenska University Hospital in May 2016. During the spring of 2017, most of the participating centres had started randomisation, but during the summer months (June-August), most of the centres needed to stop the randomisation due to the organisation of work during the summer. In some centres it turned out to be difficult to restart the recruitment after the summer break.

The included number of women in Stockholm region was n=1122 women out of the total of n=2760 women. In the Stockholm region, ultrasound examination at 41+0 gestational weeks is offered routinely, but this was not done at any of the other centres. It can be discussed if the result can be representative for Swedish women since half of the participants had an examination where women with low amniotic fluid index were excluded, or similarly if the foetus was too small for gestational age to proceed to 42+0 gestational weeks. About 10% of the examined women were excluded for these reasons (personal communication). It is difficult to determine if this may have protected the foetuses. There were no perinatal deaths in Stockholm but the number of adverse neonatal outcomes did not differ significantly between Stockholm and the other centres. Moreover, there is no convincing evidence at present that ultrasound surveillance after 41+0 gestational weeks does reduce the perinatal mortality or morbidity (Kehl et al., 2016; Nabhan & Abdelmoula, 2008, 2009).

The randomisation was done in a block design, so there was no bias in the distribution between the intervention and control groups over the other centres. Stockholm is the largest region within Study II with the largest numbers of participating centres, so it was essential to include this region in the study. Based on these small differences between the regions, it can be argued to what extent the results from Study II can be generalised or not. In any case, the strength of Study II was that the study was a national, randomised controlled multicentre trial, which included centres from both university clinics, regional, and county hospitals and both centres that performed ultrasound at 41+0 and those that did not.

9.2.2.2. Information bias

The number of actually recruited women was lower than originally expected. Variation in willingness among the participating midwives to inform about the study might have had an impact on the number of the recruited women. Participation may also have been affected by logistical problems, such as the randomisation procedure at some centres. The patient information was translated into 17 different languages, but it was still not possible to provide direct personal oral information in all of these different languages. The number of recruited women with another first language than Swedish or English might have been affected by not getting first-person information about the study through a translator, but through a relative or friend. Nearly 83% in both randomisation groups were born in Sweden, and around 6% in other Nordic countries. 1.5% were born in Europe, but outside Nordic countries, and almost 10% were born outside Europe. In addition, the language and cultural differences may have had an impact in the interest for participating in the study.

9.2.3. External validity

External validity measures the level of how the results can be generalised to other contexts or groups other than the conducted study group (Polit, 2018).

There were 14 clinics represented in the study, five university and nine county hospitals. The majority of the participating women were randomised at a prenatal clinic that belonged to a university clinic or at the university hospital, consisting of 2314 women, compared to 448, at a county hospital. Participation of both types of hospitals was a key aspect of the multicentre study; hence, it is important to compare the two.

The baseline characteristics were similar in both types of hospitals. 82.9% of the included women who were admitted to university hospitals, and 82.4% at county hospitals were born in Sweden. There was a high level of education

among the women, with 64.6% and 62.8% of them having a university degree, respectively. Some of the recruited women expressed at the randomisation procedure that they knew that research is important, and that they wanted to be part of a project to help to try to find an answer to a research question. However, some of the women expressed that they wanted to participate since they saw it as an opportunity to get an induction before 42+0 gestational weeks. It is known from previous research that a high degree of education is not uncommon among participants (Linden, Berg, Adolfsson, & Sparud-Lundin, 2018; Tjønneland et al., 2007). Thus, it can be concluded that women who were randomised at the different types of hospitals represented a largely similar population, and hence a strength of the Study II is that it can be regarded as representative for Sweden according to the baseline inclusion criteria: low risk women with a normal, singleton pregnancy.

Another strength of the study was that, regardless of which group the women were randomised to, they were assessed according to the respective centre's guidelines for induction in the same way as women who did not participate in the study, and the same level of care was delivered at each centre. The guidelines for induction are similar in all of Sweden, with only small differences in the choice of, for example, the catheter for mechanical dilatation.

Further, a strength with the data analysed in Study II was that the main analysis was on the ITT population, i.e. all the randomised women. The strength with an ITT analysis is that the population is as complete as possible, minimizing the biases (Ranganathan, Pramesh, & Aggarwal, 2016).

9.2.4. Objectivity

Objectivity is a measurement of personal beliefs or thoughts that have had an impact on the results. If the study would be conducted a second time, with other independent researchers, the same results would be obtained (Polit, 2018). The objectivity for Study II was obtained by following the study protocol, and during the analysis phase, objectivity was achieved by following the statistical analysis plan (SAP).

After clear advice from the DSMB, the study was stopped on December 21, 2018 due to the higher rate of stillbirth and neonatal death in the expectant management group. At that point, there were five stillbirths and one early neonatal death, and the difference was significant (p=0.032) compared to the early induction group. The original power analysis had showed that the trial would have needed 10,038 women to demonstrate the projected difference in the primary outcome between the groups. When the trial was stopped, just over

a quarter of this number of women had been included in the study. It is hard to calculate if the result should have shown any other significant differences between the two groups if the study should have proceeded, or if there would have been additional cases of perinatal death. However, our belief is that it would not have been ethically correct to proceed, since stillbirth and neonatal death are the most serious components in the composite primary outcome.

After the study was paused on October 15, 2018, all of the data were controlled manually before the final decision to terminate the study was made on December 21, 2019. It is a strength that persons who were not responsible for the study controlled all data manually. After the study was terminated, persons in the research and outside the research group controlled the primary and secondary outcomes again; this means that the final data have been checked both internally and externally.

9.3. Study III-IV

9.3.1. Credibility

Credibility refers to findings in the study being drawn from the original data from the participants and if there is a truthful interpretation from the original data (Korstjens & Moser, 2018; Polit, 2018). All the data, e.g. handwritten notes from the researcher, written text/journals from the informants or recorded interviews, should be transcribed verbatim (Dahlberg et al., 2008).

The women who were interviewed in Studies III and IV were informed both orally and in the patient information form about integrity. In the both Studies III and IV, the data were recorded and transcribed verbatim, so that no words would be lost. The interviewed women were named with an ID during the analysis and in the scientific article. In lifeworld research, the analysis is described as a movement from the whole to the parts and then back to the whole, this movement is central in the analysis. The researcher needs to be open for the phenomenon that emerge and during the whole analyse bridle the preunderstanding to be able to be open to what shows (Dahlberg et al., 2008). During that movement the researcher, goes back and for the whole time to really see what emerges and to not lose any data. During the data analysis a computer program, NVivo, was used to organise and store the data. This helped me to keep the original words from the women in mind. However, the program is just for organising, and not for descriptions and interpretation. In lifeworld hermeneutics this movement is called the hermeneutic circle, and was used in Study IV. The movement of going back and forth during the analysis and the

hermeneutic circle is a way to work with the original data. In Study IV and interpretation was done when the preliminary themes were formulated. There are few studies about women´s experiences of pregnancy and we used Olsson's (Olsson, 2000) metaphors even if the study was rather old, and the care during pregnancy may have changed. However, the metaphor describing pregnancy as a voyage suited the findings from the study well. The different steps in the method are described in more detail in the articles. Phenomenology was chosen to get a deeper understanding of variations and nuances of the phenomena of the women's experiences of a pregnancy ≥41 gestational weeks before and after the birth. The methods were considered suitable to the research questions in study III and IV, respectively.

9.3.2. Transferability

Transferability is the extent to which the findings can be transferred to other groups or settings, to other contexts (Korstjens & Moser, 2018; Polit, 2018). Transferability in qualitative research, such as phenomenology and lifeworld hermeneutics, is time and context dependent (Dahlberg et al., 2008). When considering the results from the two qualitative studies in the present thesis, one should be aware that the context: The city of Gothenburg and two of its suburbs, women aged 23 to 37 years, with high education (3 with secondary education; 7 with university degree), all Swedish speaking, eight primiparas and two multiparas. The results cannot be transferred to other contexts without being interpreted in relation to the new context. This does not mean that the results cannot be interesting in other contexts, but the that the findings must be related to and interpreted in the new context (Dahlberg et al., 2008).

9.3.3. Confirmability

Confirmability refers to the neutrality and objectivity of the data and the interpretations, that the researchers preunderstanding has as little impact as possible, and the level to which another researcher could confirm the findings (Korstjens & Moser, 2018; Polit, 2018).

During the whole research process, the openness for the phenomenon deserve bridling (Dahlberg et al., 2008) of the researcher's preunderstanding to be able see the phenomenon that emerges during the analysis. During the interviews, the preunderstanding really needed to be bridled. As a midwife with long clinical experience, I have heard many women's experiences of postterm pregnancy. For me it was important not to let this preunderstanding lead the interviews and data analysis. During the interviews, you always have to remind yourself to be open to phenomena. During the whole research process, a goal

was to bridle the preunderstanding, and discussions were carried out in the research group related to this aspect.

It can be discussed if the results would be the same with 10 new women or if the interviews had been done by another midwife or by a person from outside of the health care professions. Since all findings from qualitative studies are depending on the context, time and history, there may have been both similarities and differences in the new findings.

9.3.4. Authenticity

Authenticity is defined as by which level the qualitative research can show a range of different substances/realities, nuances and variations in the collection of data, analysis, and the interpretation (Polit, 2018).

In lifeworld research, it is important with variations in the data to use informants with different gender, ages, level of education, socioeconomic level, and cultures (Dahlberg et al., 2008). Regrettably, there were no women from low-income groups or women from cultures outside Sweden, and having only Swedish-speaking women is a limitation. Study III included women with different levels of education and they were from different socioeconomic groups, which increased the variation of the included women. It can be discussed what the results may show with women from other cultural contexts. The same women participated in Study IV, thus the same limitations exist in that study. However, one strength in interviewing the same women is that a deeper understanding may be reached, which increases the nuances and variations.

9.3.5. Reflexivity

Reflexivity is for the researcher a critical self-reflection, an attitude towards their own values that can have impact in the analysis process and the results. The self-reflection includes the preunderstanding, the relationship to the participants, and if and how the relationship might have an impact on the participants' answers (Korstjens & Moser, 2018).

It is important to bridle their own preunderstanding during the whole research process to be able to really the see the phenomena (Dahlberg et al., 2008). There were continuous discussions with the supervisors about the results, meaning units, clusters (phenomenology), subthemes (lifeworld hermeneutic), the essence and constituents in phenomenology and themes, and the main interpretation in the lifeworld hermeneutic.

In Study III, I did not have contact with the women before the first interview. I did the interviews in both Study III and IV. This can be both a strength and a limitation. The strength is that the women would likely have felt more comfortable with the interviewer, since we had met before, and it could be easier to express more experiences. The limitation may be that the women expressed fewer experiences because she thought that she explained something at the first interview. There is also a possibility that the interviewer was less open for what the women expressed.

10 CONCLUSIONS

There were advantages in some secondary outcomes when labour was induced at 41 (early induction group) compared to 42 gestational weeks (expectant management group), without any concomitant increase in the risk for caesarean section or instrumental vaginal delivery.

There was a higher rate of perinatal mortality in the expectant management group compared with the early induction group, and no difference in the composite perinatal outcome between the two groups.

There were higher rates of neonatal jaundice/hyperbilirubinemia, higher rates of macrosomia, and more neonates were admitted to neonatal intensive care unit in the expectant management group compared to the early induction group.

For the mother, there was a higher rate of endometritis in the early induction group, compared to the expectant management group.

The results showed that the women were in a state of limbo, a void characterised by contradiction in relation to time, giving birth, and the condition and treatment from the caregivers. Further, the women experienced the time of waiting for the labour as the start of a voyage into unknown waters.

In addition, it was found that the women need clear information and support to be strengthened in the transition from pregnancy to labour.

11 FUTURE PERSPECTIVES

- To study women's experiences of induction of a pregnancy lasting more than 41 gestational weeks.
- To analyse differences in women's experiences of giving birth between the early induction and expectant management groups.
- To analyse the cost differences between the early induction and expectant management groups.
- To analyse potential advantages and disadvantages for different methods of induction.
- To follow up the children who were born in SWEPIS.
- To study if quality of life and general self-efficacy has an impact on childbearing and birth experiences.
- To study women's experiences of late term pregnancy among women who are not born in Sweden.
- To study midwives' and obstetricians' experiences of induction.

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