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Induction of labor at 41 completed gestational weeks versus expectant management and induction at 42 completed gestational weeks

Submission date
21/03/2015

Recruitment status
No longer recruiting

Registration date
30/03/2015

Overall study status
Completed

Last Edited
09/04/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 14/04/2020:
About 15-20% of all women's pregnancies last 41 gestational weeks or longer. This leads to greater risks for the woman and the child, but we still lack sufficient evidence on how to manage these pregnancies. Nevertheless, worldwide, induction of labour before 42 (gestational) weeks has been increasingly common. The standard care in Sweden today is induction at 42 weeks. We are carrying out a study to investigate if a policy of induction of labour at 41 weeks is better for the health of children and mothers, as compared to expectant management and induction at 42 weeks. In addition, we also want to evaluate women's attitudes and experiences of early induction and expectant management and late induction of labour. Our goal is to find the optimal timing of offering induction of labour to women in late-term (41 weeks) or post-term (42 weeks) pregnancy.

Who can participate?
The study aims to recruit about 10.000 healthy pregnant women, age 18 years or over, with a normal singleton pregnancy at 41 weeks across Sweden.

What does the study involve?
Over a period of three years, pregnant women at 40 (gestational) weeks will be invited to participate in the study. Women who are interested in participating in the study are booked for a visit at the antenatal clinic or ultrasound clinic at the respective hospital at 40+6 to 41+1 weeks, where further information is given. Screening with ultrasound for oligohydramniosis and small for gestational age fetuses are performed at 41 weeks, according to local routines, in women included in the Stockholm Region. The women will be randomly allocated at 40+6 to 41+1 weeks to undergo either induction of labour the same or next day, but not earlier than at 41+0 weeks, i. e. at 41+0 to 41+2 weeks or expectant management and induction at 42+0-1 weeks. All inductions will be performed with the women staying at the hospital until delivery. The clinic's protocol and guidelines for induction and surveillance during induction will be followed. At the end of the study, we will evaluate if induction of labour at 41 weeks is better for the health of

fetuses/infants and mothers, as compared with expectant management and induction at 42 weeks. In addition, we also compare women's attitudes and experiences of induction of labour at 41 weeks and expectant management and induction at 42 weeks.

What are the possible benefits and risks of participating?
When the study was planned there was no study of sufficient size that had assessed the risks of inducing delivery at 41 weeks compared with expectant management and induction at 42 weeks. Even though the timing of the induction of the delivery may differ from the standard procedure at the delivery clinic, the delivery will be managed in accordance with the delivery clinic's existing guidelines. In other words, the same methods will be used, for example, for inducing and monitoring the delivery. If the delivery is induced the woman will remain at the hospital, which may lead to a longer hospital stay than if the delivery started of its own accord. Thus, there will be no immediate direct benefit to those taking part. However, there should be future benefits for the health of children and mothers because the results of the study are likely to stipulate the optimal timing of offering induction of labour to women at late-term (41 weeks) or post-term (42 weeks).

Where are patients recruited?
The study has been set up by the Universities of Gothenburg, Stockholm, Uppsala, Örebro and in collaboration with Falun, Varberg, Halmstad, NÄL (North Älvsborg County Hospital, Trollhättan), SÄS (Södra Älvsborg Hospital, Borås), and Visby hospitals (Sweden).

When is the study starting and how long is it expected to run for?
From September 2015 to May 2020

Who is funding the study?
This study is supported by the Swedish state under the agreement between the Swedish government and the county councils, the ALF-agreement (ALFGBG-440301, ALFGBG-718721, ALFGBG-70940, ALFGBG-426401), the Health Technology Centre at Sahlgrenska University Hospital, the Foundation of the Health and Medical care committee of the Region of Vastra Gotaland, Sweden (VGFOUREG387351, VGFOUREG640891, VGFOUREG854081), Hjalmar Svensson Foundation, the foundation Mary von Sydow, born Wijk donation fund, Uppsala-Örebro regional research council (RFR-556711, RFR-736891), Region Örebro County research committee (OLL-715501), the ALF-agreement in Stockholm (ALF-561222, ALF-562222, ALF-563222), and Centre for Clinical Research Dalarna-Uppsala University, Sweden (CKFUU-417011).

Who is the main contact?
Professor Helen Elden
helen.elden@gu.se

Previous plain English summary:
Background and study aims
About 15-20% of all women's pregnancies last 41 gestational weeks or longer. This leads to greater risks for the woman and the child, but we still lack sufficient evidence how to manage these pregnancies. Nevertheless, worldwide, induction before 42 gestational weeks has been increasingly common. The standard care in Sweden today is induction at 42 gestational weeks. We are carrying out a study to investigate if a policy of induction of labour at 41 gestational weeks is better for the health of children and mothers, as compared to expectant management and induction at 42 gestational weeks. In addition, we also want to evaluate women's attitudes and experiences of early induction and late induction of labour. Our goal is to find the optimal timing of offering induction of labour to women at late term (41 gestational weeks) or post-term (42 gestational weeks).

Who can participate?
The study aims to recruit about 10,000 healthy pregnant women, age 18 years or over, with a normal singleton pregnancy at 41 gestational weeks across Sweden.

What does the study involve?
Over a period of three years pregnant women at 40 gestational weeks will be invited to participate in the study. Women who are interested in participating in the study are booked for a visit at the antenatal clinic at the respective hospital at 41 gestational weeks. Further information is given and after written consent an ultrasound examination is performed. The women will be randomly allocated to undergo either induction of labour at 41 gestational weeks or expectant management and induction at 42 gestational weeks. All inductions will be performed with the women staying at the hospital until delivery. The clinic's protocol and guidelines for induction and surveillance during induction will be followed. At the end of the study, we will evaluate if induction of labour at 41 gestational weeks is better for the health of children and mothers, as compared to expectant management and induction at 42 gestational weeks. In addition, we also compare women's attitudes and experiences of induction of labour at 41 gestational weeks and expectant management and induction at 42 gestational weeks.

What are the possible benefits and risks of participating?
A possible benefit is that an ultrasound examination is performed at 41 gestational weeks. If the result shows low or high foetal weight or abnormal levels of amniotic fluid the women will not be included in the study but followed-up according to clinical routine. Otherwise, there will be no immediate direct benefit to those taking part. However, there should be future benefits for the health of children and mothers because the results of the study are likely to stipulate the optimal timing of offering induction of labour to women at late term (41 gestational weeks) or post-term (42 gestational weeks). There are no risks of participating in this study

Where is the study run from?
The study has been set up by the Universities of Gothenburg, Stockholm, Uppsala and Lund in collaboration with SAS (South of Alvborgs community).

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in September 2016. Participants will be enrolled on the study for a period of 3 years; however, the study will extend beyond this as we intend to follow up the children's health to the age of 4 years.

Who is funding the study?
Funding has been provided by the Foundation of the Health and Medical care committee of the Region of Vastra Gotaland, Sweden, the Health Technology Centre and grants from Swedish governmental grants to researchers in the public health service.

Who is the main contact?
Associate Professor, PhD Helen Elden

Contact information

Type(s)
Scientific

Contact name

Prof Helen Elden

Contact details
Perinatal centre
Department of Obstetrics and Gynecology
Institute of Clinical Sciences
Sahlgrenska Academy
East Hospital
Gothenburg
Sweden
416 85

Additional identifiers

Study information

Scientific Title
Induction of labour at 41 weeks versus expectant management and induction of labour at 42 weeks (SWEdish Post-term Induction Study, SWEPIS): multicentre, open label, randomised, superiority trial

Acronym
SWEPIS

Study objectives
Current study hypothesis as of 14/04/2020:
This study aims to investigate whether a policy of induction of labour at 41 weeks is superior for the health of children and mothers, as compared with expectant management and induction at 42 weeks. The literature lends some support of that induction taking place in 41-42 weeks may reduce the risk of perinatal death and meconium aspiration syndrome without increasing the risk of caesarean section or negative childbirth experiences compared with induction beyond 42 weeks. However, a large number of women needs to be induced to prevent one case of perinatal death (Numbers Needed to Treat = 469). There are also significant methodological problems in both published individual studies and systematic reviews. This is because important adverse outcomes such as perinatal mortality (PNM) and hypoxic-ischemic encephalopathy (HIE) are very rare in developed countries. Large multicentre studies are therefore needed.

The aims of the qualitative research I in the project are to describe the women's and their partner’s lifeworld experiences of prolonged pregnancy. The target number of participants for the qualitative study are 10 women and 7 partners.
Overall trial start date of qualitative study I: 19/08/2013
Recruitment start date of qualitative study I: 10/08/2013
Recruitment end date of qualitative study I: 15/12/2015

The aims of the qualitative research II in the project are to describe the women's lifeworld experiences about induction in prolonged pregnancy. The target number of participants for the qualitative study are 12 women.
Overall trial start date of qualitative study II: 12/12/2017
Recruitment start date of qualitative study II: 17/01/2018
Recruitment end date of qualitative study II: 20/12/2018

Previous study hypothesis:
This study aims to investigate whether a policy of induction of labour at 41 gestational weeks is superior for the health of children and mothers, as compared to expectant management and induction at 42 gestational weeks. The literature lends some support to induction taking place in 41-42 gestational weeks may reduce the risk of perinatal death and mekonium aspiration without increasing the risk of caesarean section or negative childbirth experiences. However, a large number of women need to be induced to prevent a case of perinatal death (NNT=469). There are also significant methodological problems in both published individual studies and systematic reviews. This is because important adverse outcomes such as PNM and HIE are very rare in developed countries. Large multicentre studies are therefore needed.
The study we propose here will show if the optimal timing of induction of labour is at 41 gestational weeks or 42 gestational weeks, define any adverse effects for mother and child, ascertain whether women find the intervention acceptable, and will calculate the costs for the NHS.

Added 01/08/2013:
The aims of the qualitative research in the project are to describe the women's and their partners lifeworld experiences about post-term pregnancy. The target numbers of participants for the qualitative study are 10 women and 7 partners.
Overall trial start date of qualitative study: 19/08/2013
Recruitment start date of qualitative study: 10/08/2013
Recruitment end date of qualitative study: 15/12/2015

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Regional Ethics Board in Gothenburg, Sweden, May 2014, Dnr: 285-14
2. Qualitative study: Regional Ethics Committee in Gothenburg, ref: 313-13
3. Qualitative study II: Regional Ethics Committee in Gothenburg, ref: Dnr T 1066-17 (added 14 /04/2020)

Primary study design
Interventional

Study design
Current study design as of 14/04/2020:
Multicentre open label randomised controlled superiority trial

Previous study design:
Multicentre register-based randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prolonged pregnancy, post-term birth

Interventions
Current interventions as of 14/04/2020:
Intervention group: Women are randomised at 40+6 to 41+1 weeks and induction is planned to

take place at 41+0 to 41+2 weeks.
Control group: Women randomised to expectant management/late induction will be induced at 42+0 weeks (and no later than 42+1 weeks). After randomisation, the women are followed-up at the ordinary antenatal clinic according to clinical routine for 41+0-42+0 weeks.

Methods of labour induction (early at 41+0-41+2 weeks or late at 42+0-42+1 weeks) will be according to the clinics' routine.

Qualitative study I:
Initially, we will recruit 10 women in gestational week 41+0 to 41+ 4 and 7 partners. If needed, more participants will be recruited. We will use open-ended interviews to collect the data. The interviews will take place in gestational week 41+0 to 41+ 4. The women will be asked to describe their experiences of prolonged pregnancy. The partners will be encouraged to describe experiences regarding everyday life with the partner with the prolonged pregnancy. The interviews will last about 60 minutes and will be tape-recorded. All interviews will be transcribed verbatim. The data will be analyzed using phenomenological analysis. The women and their partners will be re-interviewed within 4 weeks after delivery. The same questions will be asked. Thus, women will be asked to describe how they experienced their prolonged pregnancy. Consequently, the partners will be asked to describe experiences regarding everyday life with the partner with the prolonged pregnancy.

Qualitative study II:
The aim of the qualitative study II in the project is to gain a deeper understanding of women's lived experiences of induction of labour in late- and post-term pregnancies. Twelve women participating in the SWEPIS study that had their labour induced will be interviewed. The data are planned to be analyzed using reflective lifeworld phenomenology.

Data on background variables, primary, secondary, exploratory neonatal and maternal outcomes will be obtained from the Swedish Pregnancy Register, the Swedish Neonatal Quality Register and Statistics Sweden within 3 months after delivery. The Swedish Pregnancy Register and the Swedish Neonatal Quality Register are both certified national quality registers initiated by the Swedish healthcare professionals. The Pregnancy Register collects and processes information all the way from early pregnancy to a few months after birth. The Neonatal Quality Register collects data on all newborns admitted to neonatal intensive care units at birth or within 28 days of life. Study data from electronic case record form (eCRF) are linked with data from the Swedish Pregnancy Register, Swedish Neonatal Quality Register and Statistics Sweden using the unique personal identification number allocated to each person in Sweden at birth or after immigration. For all newborns with a primary outcome the medical records will be scrutinized. The same process is undertaken of the women with a diagnosis of endometritis to rule out misclassification of sepsis. To estimate selection bias, we compare the baseline characteristics and pregnancy outcomes of our study population with those of the Swedish background population. For long term follow up of mother and child we will use the National Patient Register, the Cause of Death Register and the Prescribed Drug Register.

Previous interventions:
Intervention group: Women randomised to early induction will be induced the same day as randomisation or the next day after randomisation. Thus induction will take place at GW 41+0-41+2.

Control group: Women randomised to expectant management/late induction will be induced at GW 42+0 (and no later than GW 42+1). After randomisation, the women are followed-up at the ordinary antenatal clinic according to clinical routine for GW 41+0-42+0.

Methods of labour induction (early at GW 41+0-41+2 or late at GW 42+0-42+1) will be according to the clinics' routine.

Added 17/08/2015:
Qualitative study:
Initially, we will recruit 10 women in gestational week 41+0 to 41+ 4 and 7 partners. If needed, more participants will be recruited. We will use open-ended interviews to collect the data. The interviews will take place in gestational week 41+0 to 41+ 4. The women will be asked to describe their experiences of a postterm pregnancy.
The partners will be encouraged to describe experiences regarding everyday life with the postterm pregnant partner. The interviews will last about 60 minutes and will be tape-recorded. All interviews will be transcribed verbatim. The data will be analysed using phenomenological analysis.
The women and their partners will be re-interviewed within 4 weeks after delivery. The same questions will be asked. Thus, the women will be asked to describe how they experienced their postterm pregnancy. Consequently, the partners will be asked to describe experiences regarding everyday life with the postterm pregnant partner.

Intervention Type
Mixed

Primary outcome(s)
Primary outcome will be a composite of stillbirth, neonatal mortality and neonatal morbidity. Stillbirth is defined as intrauterine foetal death of a foetus that was alive at randomisation. Neonatal mortality is defined as live births with death day 0-27. Neonatal morbidity is defined as at least one of the following variables: Apgar score <7 at 5 minutes, metabolic acidosis defined as pH <7.05 and base excess >12 mmol/l in umbilical artery or pH <7.00 in umbilical artery, HIE I-III, intracranial haemorrhage, neonatal convulsions, meconium aspiration syndrome (MAS), mechanical ventilation, obstetric brachial plexus injury.

Key secondary outcome(s)
Current secondary outcome measures as of 14/04/2020:
1. Secondary neonatal outcomes
1.1. Perinatal mortality, stillbirths and neonatal mortality assessed from patient notes on live births with death at 0 to 27 days
1.2. Stillbirths assessed from patient notes at 0 days
1.3. Neonatal mortality assessed from patient notes on live births with death at 0 to 27 days
1.4. Neonatal morbidity (at least one of the following variables: Apgar score <7 at 5 minutes, metabolic acidosis defined as pH <7.05 and base excess >12 mmol/l in umbilical artery or pH <7.00 in umbilical artery, HIE I-III, intracranial hemorrhage, neonatal convulsions, meconium aspiration syndrome (MAS), mechanical ventilation within the first 72 hours, and obstetric brachial plexus injury)
1.5. Neonatal health assessed by the Apgar score <7 at 5 minutes
1.6. Metabolic acidosis defined as pH <7.05 and base excess >12 mmol/l in umbilical artery or pH <7.00 in umbilical artery
1.7. Hypoxic-ischaemic encephalopathy assessed using HIE I-III
1.8. Intracranial hemorrhage
1.9. Neonatal convulsions
1.10. Meconium aspiration syndrome (MAS)
1.11. Mechanical ventilation within the first 72 hours
1.12. Obstetric brachial plexus injury

2. Other secondary neonatal outcomes
2.1. Admittance to neonatal intensive care unit
2.2. Birth weight (grams)
2.3. Macrosomia (≥4500 g)
2.4. Therapeutic hypothermia
2.5. Neonatal jaundice requiring phototherapy or exchange transfusion
2.6. Pneumonia, Sepsis
2.7. Cerebral palsy
3. Exploratory neonatal outcomes
3.1. Neonatal hypoglycemia, defined as P-glucose concentration <2.6 mmol/L after three hours
3.2. Birth trauma (fracture of long bone, clavicle, or skull, other neurological injury, retinal hemorrhage, or facial nerve palsy)
3.3. Small for gestational age
3.4. Large for gestational age
4. Secondary maternal outcomes in the main study and the substudies
4.1. Chorioamnionitis
4.2. Use of oxytocin
4.3. Use of epidural anesthesia
4.4. Shoulder dystocia
4.5. Caesarean section
4.6. Assisted vaginal delivery (vacuum extraction or forceps)
4.8. Perineal lacerations III-IV
4.9. Postpartum hemorrhage (>1000 ml)
4.10. Duration of labour (minutes)
4.11. Wound infection
4.12. Urinary tract infection
4.13. Endometritis, sepsis
4.14. Breastfeeding at discharge and 4 weeks after childbirth
4.15. Women's attitudes and experiences at randomisation (Sub study)
The following data on women's attitudes, experiences and health-related quality of life will be collected by questionnaires (web based or postal):
at randomisation in subpopulations in Gothenburg, Falun and Örebro
4.15.1 Personality (Big Five)
4.15.2 Health related quality of life (Euro-Qol –VAS & Euro-Qol-5D)
4.15.3 Depression/anxiety (HADS),
4.15.4 Self-efficacy (The General Self-Efficacy Scale [GES])
4.16. Women's attitudes and experiences 3 months after randomisation.
The following data on women's attitudes, experiences and health-related quality of life will be collected by questionnaires (web-based or postal) 3 months after randomisation in subpopulations in Gothenburg, Falun and Örebro
4.16.1 Health-related quality of life (Euro-Qol –VAS & Euro-Qol-5D)
4.16.2 Depression/anxiety (HADS)
4.16.3 Self-efficacy (The General Self-Efficacy Scale [GES])
4.16.4 The Childbirth Experience Questionnaire (CEQ)
5. Exploratory maternal outcomes
5.1. Cervical tear
5.2. Uterine rupture
5.3. Hypertensive disorders of pregnancy (pre-eclampsia,
gestational hypertension, eclampsia)
5.4. Venous thromboembolism
5.5. Duration of stay in hospital
5.6. Admission to intensive care unit

5.7. Mortality within 42 days
5.8. For women from clinics outside Gothenburg, Falun and Örebro we will register data on satisfaction with delivery (VAS 1-10) from medical records
6. Women's experiences of a prolonged pregnancy measured through open-ended interviews with women and their partners.
7. Cost-effectiveness analyses (sub study). Economic cost consequences (measured as the cost per birth) of early induction of labour at late term (at 41 GW) compared with expectant management and late induction (at 42+0 GW) in healthy women with a singleton foetus in cephalic presentation. Cost-effectiveness analyses will be performed based on the cost per life-year gained and cost per quality-adjusted life year (QALY) gained. Costs taken into consideration will be both costs for the woman and the child. For the women: visits to midwife/obstetrician and antenatal surveillance from randomisation to discharge from hospital after delivery, the delivery cost including length of stay at hospital (mother and infant), time and examinations, drugs used for induction of labor, other drugs, material use, treatments, costs for employees and hospital facilities. For the infant: treatment at neonatal ward/children's hospital if needed in connection to the time of delivery.

Previous secondary outcome measures:
1. Data on background variables and secondary maternal outcomes will be obtained from the Pregnancy Register about 3 months after delivery (the Pregnancy Registry is a Certified National Quality Registry initiated by the Swedish Healthcare that collect and process information all the way from early pregnancy to a few months after birth).
1.1. Chorioamnionitis
1.2. Use of oxytocin
1.3. Use of epidural anesthesia
1.4. Shoulder dystocia
1.5. Caesarean section
1.6. Assisted vaginal delivery
1.7. Forceps
1.8. Vacuum extraction
1.9. Perineal lacerations III-IV
1.10. Postpartum hemorrhage (>1000 ml) (no/yes)
1.11. Duration of labour (minutes)
1.12. Wound infection
1.13. Urinary tract infection
1.14. Endometritis, sepsis (no/yes)
2. Breastfeeding at 3 months and 6 months
3. Patient-, Cause of Death-, and Prescribed Drug Registers after delivery
4. The following data on women's attitudes, experiences and health-related quality of life will be collected, only in the Region Vastra Götaland subpopulation, by questionnaires (web based or postal) after randomisation:
4.1. Personality (Big Five)
4.2. Depression/anxiety (HADS)
4.3. Health related quality of life (Euro-Qol –VAS & Euro-Qol-5D)
4.4. Self-efficacy (The General Self-Efficacy Scale (GES)
5. The following data on women's attitudes, experiences and health-related quality of life will be collected, only in the Region Vastra Götaland subpopulation, by questionnaires (web-based or postal) 3 months after randomisation:
5.1. Health-related quality of life (Euro-Qol –VAS & Euro-Qol-5D)
5.2. The General Self-Efficacy Scale (GES)
5.3. Depression/anxiety (HADS)
5.4. The Childbirth Experience Questionnaire (CEQ)

6. For counties with the same Obstetrix record we will register data on satisfaction with delivery (VAS 0-10)
7. Cost-effectiveness analyses will be performed comparing induction at GW 41+0 with induction at GW 42+0. For example: the woman's visits to midwife and obstetrician, antenatal surveillance, sick leave, quality-adjusted life year (QUALY), length of stay at hospital (mother and infant), time and examinations, drugs used for induction of labor, other drugs, material use, treatments, costs for employees and hospital facilities. For the infant: visits to neonatal ward/children's hospital and to nurse and MD at Swedish Child Health care during the first 3 months after birth.
8. Data on neonatal outcomes will be obtained from the SNQ (Swedish Neonatal Quality Register) after delivery:
8.1. Admittance to neonatal intensive care unit,(no/yes)
8.2. Birth weight (grams)
8.3. Macrosomia (no/yes)
8.4. Shoulder dystocia ,(no/yes),
8.5. Apgar score <4 at 5 minutes ,(no/yes)
8.6. Therapeutic hypothermia ,(no/yes)
8.7. Neonatal jaundice (no/yes)
8.8. Treatment for neonatal jaundice for example: light therapy (no/yes), bloodtransfusion ,(no /yes),
8.9. Pneumonia ,(no/yes)
8.10. Sepsis ,(no/yes)
8.11. Cerebral palsy (no/yes)
9. The Swedish Child Health Quality Register will be used for collection of data on breastfeeding at 6 months and 1 year. We intend to follow neurodevelopment at childhood at 2 years and 4 years and death during the first 4 years of life.

Added 17/08/2015:
Qualitative study:
Open-ended interviews will be conducted with 10 women and 7 partners before the start of the RCT. This part of the study will be focused of the women's experiences of a postterm pregnancy. Their partners will be interviewed of their experiences regarding everyday life with the postterm pregnant partner.

Completion date
31/05/2020

Reason abandoned (if study stopped)
The trial was stopped early due to ethical reasons, safety and a statistically significant difference in stillbirths/neonatal mortality. No perinatal deaths occurred in the early induction group but six occurred in the expectant management group (five stillbirths and one early neonatal death; P=0.03).

Eligibility

Key inclusion criteria
Healthy women ≥18 years old with a normal live singleton pregnancy in cephalic presentation at 41+0 GW, who is able to understand oral and written information

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
2760

Key exclusion criteria
1. Women with previous caesarean section or other uterine surgery
2. Pregestational and insulin-dependent gestational diabetes
3. Hypertensive disorders in pregnancy including preeclampsia
4. Multiple pregnancy
5. Foetus in breech or transverse position
6. Oligohydramniosis (amniotic fluid index <50 mm or deepest vertical pocket <20 mm)
7. Small for gestational age (<-22% according to a Swedish reference)
8. Antenatally detected foetal malformations and contraindications to vaginal delivery such as placenta previa

Date of first enrolment
20/05/2016

Date of final enrolment
20/12/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital
Perinatal Centre
Department of Obstetrics and Gynecology
Institute of Clinical Sciences
Sahlgrenska Academy
East Hospital
Gothenburg
Sweden
416 85

Study participating centre
Karolinska University Hospital
Karolinska vägen
Stockholm
Sweden
171 76

Study participating centre
Uppsala University hospital
Akademiska sjukhuset
Uppsala
Sweden
751 85

Study participating centre
South Alvsborgs Hospital
Brämhultsvägen 53
Boras
Sweden
-

Study participating centre
Karolinska University Hospital Huddinge
Hälsovägen 13
Huddinge
Sweden
141 57

Study participating centre
South Hospital
Sjukhusbacken 10
Stockholm
Sweden
118 61

Study participating centre
Danderyds hospital
Svärdvägen 11

Danderyd
Sweden
182 33

Study participating centre
Södertälje hospital
Rosenborgsgatan 6-10
Södertälje
Sweden
152 40

Study participating centre
University hospital Örebro
Södra Grev Rosengatan 18
Örebro
Sweden
703 82

Study participating centre
Falun Hospital
-
Falun
Sweden
791 82

Study participating centre
Hallands Hospital
Lasarettsvägen 6
Halmstad
Sweden
302

Study participating centre
North Älvsborg Hospital (NÄL)
-
Trollhättan
Sweden
461 85

Study participating centre
Varbergs hospital
Träslövsvägen 68
Varberg
Sweden
432 37

Study participating centre
Visby hospital
Visborgsalle’n 19
Visby
Sweden
621 50

Sponsor information

Organisation
Sahlgrenska University Hospital

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Government

Funder Name
The Foundation of the Health and Medical Care Committee of the Region Vastra Gotaland

Funder Name
Stiftelsen Handlanden Hjalmar Svenssons

Alternative Name(s)
Hjalmar Svensson Foundation, Hjalmar Svensson's Research Foundation, Stiftelsen Hjalmar Svenssons

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Health Technology Centre (HTA) at Sahlgrenska University Hospital

Funder Name
Stiftelsen Mary von Sydows, född Wijk, donationsfond

Alternative Name(s)
Mary von Sydow Foundation, Mrs Mary von Sydow Foundation, Stiftelsen Mary von Sydows Donationsfond, Stiftelsen Fru Mary von Sydows

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Uppsala-Örebro Regional Research Council

Funder Name
Centre for Clinical Research Dalarna-Uppsala University

Funder Name
ALF-agreement Region Vastra Gotaland

Funder Name
ALF-agreement Region Stockholm

Funder Name
ALF-agreement for Region Örebro County, Regional Research Council Uppsala-Örebro and Region Örebro Research Council

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/11/2019	22/11/2019	Yes	No
Results article	childbirth experience results	07/04/2021	09/04/2021	Yes	No
Protocol article	protocol	07/03/2016		Yes	No