

Measurement of cervical length with vaginal ultrasound in midgestation in asymptomatic women with a singleton pregnancy to predict preterm delivery

Submission date 22/09/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 28/09/2016	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 11/10/2023	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The length of a women's cervix (cervical length) during pregnancy can affect the chances of premature labour. If a expectant mother has a short cervix, they can be at risk of going into premature labour and, therefore, premature birth of their baby. During pregnancy, the cervix (which is usually closed and rigid) with soften up over time, become shorter and open up as the baby grows and the body prepares to give birth. If the cervix begins to open too soon, premature birth may result. This study is looking at pregnant women with no symptoms pregnant with one baby, measuring the length of their cervix using vaginal ultrasound twice: at 18-20 weeks and at 21-23 weeks. The aims are to get an estimate of how many women have a short cervix during pregnancy, when it is best to measure the cervix to determine whether it is short, at what time is shortening of the cervix more likely to cause premature birth and how good the methods used to determine a short cervix are.

Who can participate?

Healthy pregnant women at between 18-20 weeks with one baby.

What does the study involve?

Participants have ultrasound examinations of their cervix at 18-20 weeks into their pregnancy and again at 21-23 weeks. At each session, the measurements are taken three times. The examination is carried out by a specially trained midwife. The women are not told the results of the measurements. Data is then collected to determine whether the method can successfully predict premature birth.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Five hospitals in Sweden.

When is the study starting and how long is it expected to run for?
January 2014 to May 2017

Who is funding the study?

1. Swedish Research Council
2. Regional R & D Council, Uppsala / Örebro
3. Center for Clinical Research Dalarna
4. Southern Älvsborg Hospital
5. Regional R & D funds Västra Götaland
6. Hjalmar Svensson Research Fund
7. Lön (County Councils' Mutual Insurance)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

2014-10104-117089-114 The Swedish Research Council

Study information

Scientific Title

Measurement of cervical length with vaginal ultrasound in the second trimester in asymptomatic women with a singleton pregnancy to predict preterm delivery: a Swedish multi-center observational study

Study objectives

The general aim is to collect information to estimate if screening for preterm birth (PTB) with cervical length measurements at midgestation using ultrasound and prophylactic progesterone treatment if the cervix is short is potentially costeffective in Sweden. The specific aims are to in a Swedish population:

1. Estimate the prevalence of "short" cervix as measured by vaginal ultrasound at midgestation in asymptomatic women with a singleton pregnancy
2. Find the optimal cervical length cutoff to predict PTB in asymptomatic women with a singleton pregnancy
3. Estimate the sensitivity and specificity with regard to PTB of "short" cervix as measured by vaginal ultrasound (using different measurement techniques and definitions) at midgestation in asymptomatic women with a singleton pregnancy
4. Define the optimal gestational weeks (in the window from 18 to 23 gestational weeks) to measure cervical length to predict PTB in asymptomatic women with a singleton pregnancy
5. Investigate if a shortening of the cervix between gestational week 1820 and 2123 is more predictive of PTB than a single measurement of cervical length in asymptomatic women with a singleton pregnancy
6. Based on the results of 1., 2., 3., 4. and 5. and knowledge of the prevalence of PTB in singleton pregnancies in Sweden calculate the sample size of a Swedish randomized controlled trial to investigate the effect on PTB and neonatal outcome of screening asymptomatic women with a singleton pregnancy with ultrasound measurement of cervical length followed by progesterone treatment if the cervix is "short"

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical committee at University of Gothenburg, Sweden, 13/11/2013 (ref: 825-13), 17/01/2014 (ref: T053-14), 08/12/2015 (ref: T972-15) and 25/02/2016 (ref: T122-16)

Primary study design

Observational

Study design

Multicentre prospective observational study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Pregnancy

Interventions

This is a Swedish multicentre prospective observational study. where healthy asymptomatic women with a singleton pregnancy will be examined with transvaginal ultrasound and measurement of cervical length during midtgestation.

Ultrasound examinations of the cervix are carried out by specially trained midwives, who have undergone standardized theoretical education and practical training. A certification system specially designed for this project is in place. The ultrasound examinations are performed vaginally with the woman in the lithotomy position with an empty urinary bladder. The vaginal

ultrasound probe is slowly introduced into the vagina until the cervix becomes visible. Care is taken not to exert undue pressure on the cervix: the anterior and posterior lips of the cervix should appear equally thick. Ideally, the cervical canal should be horizontal in the image. The length of the closed cervical canal (the line made by the interface of the mucosal surfaces) is measured as a straight line between the internal and external cervical os. If the isthmus is present its length is measured separately. Each measurement is taken three times, and all three are recorded. Images are stored for quality assessment.

These measurements are taken at 18+0-20+6 gestational weeks and 21+0-23+6 gestational weeks.

The women themselves and all medical staff are blinded to the results of the cervical length measurements. However, an ultrasound finding of bulging amniotic membranes is disclosed.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Ability of sonographic cervical length to predict preterm birth < 33 weeks, expressed as the area under the receiver operating characteristic curve (ROC) sensitivity, specificity, positive and negative likelihood ratio.

Key secondary outcome(s)

Ability of sonographic cervical length to predict spontaneous PTB <33 + 0 gestational weeks and for total and spontaneous PTB <28 + 0, <29 + 0, <30 + 0, <31 + 0, <32 + 0, <34 + 0 and < 35 + 0 gestational weeks.

All calculations will be made for:

1. the length of the closed cervical canal
2. if the isthmus is present its length is measured separately
3. from the external cervical os to the apparent (virtual) inner cervical os (if isthmus is present)
4. the length of the closed cervical canal + the isthmus.

Each measurement is taken three times and all three are recorded. Calculations will be made for the minimum, maximum and mean value and separately for measurements taken at 18 + 0 - 20 + 6 gestational weeks and 21+ 0 - 23 + 6 gestational weeks. using the ROC curves, the optimal method for measuring cervical length (which week, which measurement) and the optimal cervical length cutoff of the optimal method to predict PTB will be identified. The ability of a change in cervical length between the first (at 18 + 0 - 20 + 6) and the second (at 21 + 0 - 23 + 6) cervical length measurement to predict PTB. The prevalence of "short cervix" (using different definitions) will be calculated.

Completion date

01/11/2017

Eligibility

Key inclusion criteria

1. Asymptomatic women > 18 years old
2. With a live healthy singleton pregnancy in gestational week 18+0-20+6
3. 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

11486

Key exclusion criteria

1. Fetal malformation
2. Rupture of membranes
3. Current vaginal bleeding
4. Ongoing miscarriage
5. Cerclage in situ
6. Current progesterone treatment at the time of recruitment

Date of first enrolment

01/05/2014

Date of final enrolment

30/06/2017

Locations**Countries of recruitment**

Sweden

Study participating centre

Sahlgrenska University Hospital

Gothenburg

Sweden

41685

Study participating centre

Skåne University Hospital
Malmö/Lund
Sweden
20502

Study participating centre
Karolinska University Hospital Solna/Huddinge
Stockholm
Sweden
17176

Study participating centre
Falun's Hospital
Falun
Sweden
79182

Study participating centre
Örebro University Hospital
Örebro
Sweden
70185

Sponsor information

Organisation
Region Västra Götaland

ROR
<https://ror.org/00a4x6777>

Funder(s)

Funder type
Research council

Funder Name
Swedish Research Council, Vetenskapsrådet

Funder Name

Regional R & D Council, Uppsala / Örebro (Regionala FOU rådet Uppsala/Örebro)

Funder Name

Centrum för Klinisk Forskning Dalarna

Alternative Name(s)

Center for Clinical Research Dalarna, CKF

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Southern Älvsborg Hospital (SÄS, Forskningsenhet)

Funder Name

Regional R & D funds Västra Götaland (VGR Regionala FOU medel)

Funder Name

Hjalmar Svensson Research Fund (Handlanden Hjalmar Svensson, Göteborg)

Funder Name

Löf (County Councils' Mutual Insurance)

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		01/01/2021	30/08/2022	Yes	No
Results article		22/07/2021	30/08/2022	Yes	No
Results article		01/06/2022	30/08/2022	Yes	No
Results article		14/09/2022	11/10/2023	Yes	No
Interim results article		01/11/2020	06/12/2021	Yes	No
Protocol file			01/09/2022	No	No
Statistical Analysis Plan	Reproducibility study version 1.0	28/10/2017	30/08/2022	No	No
Statistical Analysis Plan	main study version 1.0	13/03/2013	30/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes