

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

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<b>Registration date</b> 28/09/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/10/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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?

Dr Ulla-Britt Wennerholm  
ulla-britt.wennerholm@vgregion.se

### **Study website**

<http://www.medscinet.com/cervixstudien/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Ulla-Britt Wennerholm

### **ORCID ID**

<http://orcid.org/0000-0003-2475-2226>

### **Contact details**

Sahlgrenska Universitetssjukhuset, Östra  
Göteborg  
Sweden  
41685  
+46313435580  
ulla-britt.wennerholm@vgregion.se

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### **Secondary identifying numbers**

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)

## **Study design**

Multicentre prospective observational study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Screening

## **Participant information sheet**

### **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 measure**

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.

### **Secondary outcome measures**

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.

**Overall study start date**

01/01/2014

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

11000

**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

**Sponsor details**

Regionens Hus  
Vänersborg  
Sweden  
46280  
+46104410000  
regionenshus@vgregion.se

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.vgregion.se>

**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

**Publication and dissemination plan**

The results of the trial is expected to be presented during 2018 in scientific papers and at conferences.

**Intention to publish date**

01/11/2018

**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?
<a href="#">Interim results article</a>		01/11/2020	06/12/2021	Yes	No
<a href="#">Results article</a>		01/01/2021	30/08/2022	Yes	No
<a href="#">Results article</a>		22/07/2021	30/08/2022	Yes	No
<a href="#">Results article</a>		01/06/2022	30/08/2022	Yes	No
<a href="#">Statistical Analysis Plan</a>	Reproducibility study version 1.0	28/10/2017	30/08/2022	No	No
<a href="#">Statistical Analysis Plan</a>	main study version 1.0	13/03/2013	30/08/2022	No	No
<a href="#">Protocol file</a>			01/09/2022	No	No



[Results article](#)

14/09/2022    11/10/2023    Yes    No