Assessment of cervical SofTening and the Prediction of Preterm birth

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The aim of this study is to evaluate the predictive capacity of cervical softening and risk of PTB.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON51730

Source
ToetsingOnline

Brief title
STIPP study

Condition

- Maternal complications of pregnancy

Synonym
preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Pregnolia AG

Intervention

Keyword: Cervical softening, preterm birth

Outcome measures

Primary outcome

Asymptomatic cohort: Spontaneous PTB before 34 weeks of gestation.

Symptomatic cohort: Delivery within seven days.

Secondary outcome

1. Evaluate the diagnostic value and accuracy of the combination of cervical softening and transvaginal cervical length measurement* to predict PTB before 34 weeks of gestation or delivery within seven days.

2. Evaluate the diagnostic value and accuracy of cervical softening to predict PTB before;

- 37 weeks of gestation
- 34 weeks of gestation
- 32 weeks of gestation
- 28 weeks of gestation

3. Evaluate the diagnostic value and accuracy of the combination of cervical softening and transvaginal cervical length* measurement to predict PTB before;

- 37 weeks of gestation
- 34 weeks of gestation
- 32 weeks of gestation
- 28 weeks of gestation

4. Evaluate the diagnostic value and accuracy of cervical softening to predict latency time (interval between inclusion and delivery in days)

5. Evaluate the diagnostic value and accuracy of the combination of cervical softening and transvaginal cervical length measurement* to predict latency time (interval between inclusion and delivery in days)

6. To create a prediction model to optimally predict spontaneous PTB before 34 or delivery within seven days with the use of the following predictors (in hierarchical order):

- Cervical stiffness index
- Transvaginal cervical length
- Fetal Fibronectin#
- Twin gestation
- Severity of previous spontaneous PTB
- Cervical surgery
- Inter-pregnancy interval
- Urinary tract infection
- Family history
- Social economic status
- Smoking
- BMI

Study description

Background summary

Preterm birth (PTB) is amongst the leading causes of perinatal and childhood morbidity and mortality. Therefore, accurate identification of pregnant women at high risk of PTB is important. Identifying these women, enables obstetric healthcare professionals to apply interventions to postpone delivery and/or to prevent PTB to improve perinatal and childhood outcomes.
Currently, transvaginal cervical length measurement is used to screen asymptomatic pregnant women with a history of PTB to identify women requiring a cerclage. In symptomatic women, presenting with threatened (PTB), cervical length in combination with the fibronectin test is used to identify women at high risk to deliver within 7 days of presentation.. However, the predictive capacity of transvaginal cervical length measurement is limited. In pregnant women with a history of PTB, it only identifies a proportion of women who will have recurrent PTB. For symptomatic women, 30-60% of these women admitted to the hospital, do not deliver within seven days, leading to overtreatment of these women.
Since cervical softening is a precursor of cervical shortening, effacement and dilatation, cervical softening is a promising new marker that is based on tissue elasticity. It can be measured with the CE-marked Pregnolia® System for accurate characterization of cervical softening status. It provides a value for tissue elasticity on a continuous scale.
A previous study has shown that softening of the cervix can be detected before shortening of the cervix. The Pregnolia® System may allow to detect women at risk for PTB earlier compared to traditional transvaginal ultrasound that measures shortening of the cervix, and therefore may prove useful for a more accurate risk assessment of PTB.

Study objective

The aim of this study is to evaluate the predictive capacity of cervical softening and risk of PTB.

Study design

single centre prospective cohort study.
The Pregnolia® System will be investigated in two different cohorts:
1. Asymptomatic women with a history of PTB
2. Symptomatic women with symptoms of threatened PTB

Study burden and risks

Asymptomatic cohort:

Standard care for participating women encompasses biweekly visits to the Preterm Birth Clinic of the Amsterdam UMC. As part of routine care a transvaginal cervical length measurement is performed to screen for short cervical length. In case of participation in the study, cervical softening will be measured simultaneously.

Symptomatic cohort:
All women presenting with threatened PTB undergo transvaginal cervical length measurement and a fetal fibronectin test (fFN-test) to assess the risk of delivery within seven days. During this risk assessment cervical softening will be measured simultaneously.

Procedure of Pregnolia® System:
The procedure is equal for both cohorts and consists of speculum placement and measurement of cervical softening with the CE-marked Pregnolia® System for accurate characterization of cervical softening. The procedure is completed within 75 seconds and is pain free and harmless

Other study procedures:
In both cohorts a structured questionnaire will be used to screen for additional risk factors for PTB. Patient experience will be monitored as well as information on safety of the cervical softening measurement.

Benefit and harm:
There is no direct benefit from participation because obstetric healthcare providers will be blinded for the results of the cervical softening measurement. However the burden and risks for participating women will be minimal. Provided care will be according to current national and international guidelines.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Age 18 years or above.
- Ability to understand Dutch or English (both spoken and written).
- Ultrasound-based gestational age determined by measurement of crown rump length (CRL) determined between 9 and 11 weeks of gestation.
- Singleton and twin pregnancies.
- Medical history of spontaneous PTB before 34 weeks of gestation OR Threatened PTB between 24 and 34 weeks of gestation.

Exclusion criteria

- Under 18 years of age.
- Signs of intrauterine infection.
- Obstetric indication for immediate delivery (advanced labor, cord prolapse, abruption, signs of fetal distress).
- Confirmed fetal abnormality.
- Confirmed preterm rupture of membranes.
- Confirmed vasa / placenta praevia.
- Severe vaginal bleeding and light bleeding that cannot be stopped.
- Signs of imminent labor such as blood loss, regular contractions.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2022
Enrollment:	390
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80642.018.22