Benefits of Assessment of the Lower uterine segment in predicting a successful trial of labour in women with a history of one previous caesarean section

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To develop a prediction model for women with one previous caesarean section by combining assessment of the lower uterine segment with an extensive antepartum history taking and postpartum follow up.

Ethical review	Approved WMO
Status	Completed
Health condition type	Maternal complications of labour and delivery
Study type	Observational invasive

Summary

ID

NL-OMON55554

Source
ToetsingOnline

Brief title
LUS-Study

Condition

- Maternal complications of labour and delivery

Synonym
caesarean section

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cesarean section, lower uterine segment, sonography, trial of labor

Outcome measures

Primary outcome

successful vaginal birth

Secondary outcome

uterine rupture

poor neonatal outcome

poor maternal outcome

Study description

Background summary

With the rising amount women giving birth by caesarean section in the Netherlands and beyond, there is also an increase of women having a trial of labor after caesarean. Vaginal birth after a previous caesarean section had a lower success rate and is associated with a high rate of repeat caesareans and a higher risk adverse events for mother and fetus.
A rare but devastating complication is a uterine rupture. A recent review showed a relation between the thickness of the lower uterine segment and risk of scar defects and dehiscence. Differences between the way of measuring and the primary outcomes have made it difficult to compare the existing literature. Several attempts have been made to develop a prediction model for successful VBAC, all based on maternal characteristics, medical history, none of them have taken into account the aspects and thickness of the lower uterine segment.

Study objective

To develop a prediction model for women with one previous caesarean section by combining assessment of the lower uterine segment with an extensive antepartum

history taking and postpartum follow up.

Study design

We will perform a closed observational cohort study, that is, the results of the measurement of the lower uterine segment will not be communicated to either patient nor obstetric health care provider.
We recruit pregnant women referred to the AMC early in pregnancy for routine first trimester ultrasonography. Patients with a singleton pregnancy and with one previous CS are counselled to undergo lower uterine measurement in succesion of routine ultrasonographic examinations during pregnancy.
Exclusion criteria are previous myomectomy or prior classical caesarean
Eligible women give written informed consent and approval is attained from the METC of the AMC.
Eligible participants undergo routine ultrasound examination and additional transvaginal measurement of the lower uterine segment in 1st , 2nd and 3rd trimester.
Lower uterine segment evaluation is performed by transvaginal ultrasound with a transvaginal 7 MHz frequency probe. All ultrasound assessments are performed by experienced physician-ultrasonographists appropriately trained in performing this measurement. The examinations are performed with a near empty bladder. A clear view of the LUS view is obtained in the midsagittal plane. The first TVU is performed in the 12 week of pregnancy. This examination we try to identify the uterine scar and measure the dimensions of the scar. Figure *
During 2nd and 3rd trimester LUS examination of the lower uterine thickness will be performed in week 20 during the fetal anatomy screening examination an in week 34 together with biometry assessment.
A sagittal scan from side to side is performed and the thinnest measurement from the mucosa of the bladder to the chorioamniotic membrane as taken up to a tenth of a millimetre.
During the first trimester extensive history will be taken and data is collected concerning prior pregnancy outcomes. During the concurrent examination developing pregnancy related complications are noted. The mode of delivery is chosen solely based on the judgement of the obstetric caregivers who are blinded for LUS measurements. After delivery pregnancy outcomes are retrieved.

Study burden and risks

Women will undergo in succession to the routine scans in 1st 2nd and 3rd trimester transvaginal sonographic evaluation of the lower uterine segment. This can be done within 5 minutes time. Women will in general have no discomfort during examination and there are no associated risks concerning the pregnancy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

1e trimester pregnancy
singleton pregnancy
one previous caesarean section

Exclusion criteria

multiple gestation
>one previous caesarean section

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-06-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL38697.018.11