Reducing primary and secondary cesarean delivery rates in women with a previous cesarean delivery using electrohysterography: randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26343

Source
Nationaal Trial Register

Brief title
EHG-VBAC trial

Health condition

Trial of labor after previous cesarean delivery

Sponsors and support

Primary sponsor: Máxima MC Veldhoven
Source(s) of monetary or material Support: n/a

Intervention

Outcome measures

Primary outcome

Percentage of successful TOL will be the primary outcome measure in this study.

Secondary outcome

Secondary outcome measures will be reason for secondary CD, percentage instrumental vaginal deliveries, oxytocin augmentation, complications during delivery (e.g. uterine ruptures), maternal blood loss, duration of first and second phase of labor, neonatal outcomes such as Apgar score <7 after 5 minutes, neonatal metabolic acidosis defined as pHa<7.05 and BD>12, admission to neonatal intensive care unit and perinatal mortality.

Study description

Background summary

We hypothesize that electrohysterography (EHG) will help to increase the rate of successful trial of labor after cesarean derlivery. Patients will be randomized to either uterine monitoring using tocodynamometry or electrohysterography during a trial of labor after previous cesarean delivery.

Study objective

We hypothesize that the percentage of successful TOL will increase with the use of EHG because EHG provides more accurate assessment of UA, allowing for better optimization of the contraction pattern during labor. Besides, more reliable monitoring will make doctors and patients feel safer during a TOL and therefore making a successful TOL more likely. We also hypothesize that EHG is more capable of detecting an uterine rupture in early stage than TOCO. EHG can show subtle changes in baseline, whereas for TOCO the baseline is not reliable at all.

Study design

First inclusion 22-11-2017

Intervention

Electrohysterography as method of monitoring uterine activity during a trial of labor after previous cesarean delivery

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Pregnant women aged 18 years or older with previous CD
- Singleton pregnancy
- 37 to 41 weeks of gestation
- Cephalic presentation
- Spontaneous onset of labor
All patients included for this study must provide informed consent.

Exclusion criteria

- Estimated fetal weight >4000g
- Maternal age above 40 years
- Classical vertical or T- or J-incision of uterus
- Previous uterine rupture
- Cesarean delivery in previous 12 months
- Labor dystocia or failed induction as indication for previous cesarean delivery
- Placenta praevia, vasa praevia, fetus with relevant congenital malformation that can influence the delivery mode
- Primary infection of genital herpes simplex or active HIV
- Suspicion for abruptio placentae
- Dermatologic diseases, external or internal electrical stimulator and water birth.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	22-11-2017
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-12-2019
Application type:	First submission

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
NTR-new	NL8199
Other	Ethical approval committee of Maternal and Child Hospital of Shijiazhunag (China) : 20171018

Study results