

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

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Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26343

Bron

Nationaal Trial Register

Verkorte titel

EHG-VBAC trial

Aandoening

Trial of labor after previous cesarean delivery

Ondersteuning

Primaire sponsor: Máxima MC Veldhoven

Overige ondersteuning: n/a

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

First inclusion 22-11-2017

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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040-8888380

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	22-11-2017
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	02-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8199
Ander register	Ethical approval committee of Maternal and Child Hospital of Shijiazhuang (China) : 20171018

Resultaten