Electrohysterography compared to external tocodynamometer and intra-uterine pressure catheter for uterine contraction monitoring during term labor.

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Monitoring contractions during labor can be challenging. Currently, external tocodynamometry and the intrauterine pressure catheter are used as monitoring technique. The external tocodynamometer is a safe option with poor accuracy, whereas an...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23485

Bron
NTR

Verkorte titel
W3-study

Aandoening

Uterine contraction monitoring during term labor with three different techniques.

Ondersteuning

Primaire sponsor: Board of Management Máxima Medical Center, Veldhoven, the Netherlands
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the sensitivity of electrohysterography to monitor contractions in pregnant women during term labor. Sensitivity is defined as the percentage of correctly identified contractions that were simultaneously detected by an intrauterine pressure catheter. Sensitivity of electrohysterography will also be compared with sensitivity of external tocodynamometry.

Toelichting onderzoek

Achtergrond van het onderzoek

In this observational prospective study, pregnant women in term active labor will be simultaneously monitored with EHG, TOCO and IUPC. The goal is to determine the sensitivity of EHG and to compare EHG with TOCO.

Doel van het onderzoek

Monitoring contractions during labor can be challenging. Currently, external tocodynamometry and the intrauterine pressure catheter are used as monitoring technique. The external tocodynamometer is a safe option with poor accuracy, whereas an intrauterine pressure catheter provides a quantifiable measure but is invasive. We want to study the performance of a new monitoring system based on real-time electrohysterography: PUREtrace (Nemo Healthcare, Eindhoven, the Netherlands). Electrohysterography has several potential advantages: it is non-invasive, accurate, reliable and applicable on a continuous basis. Moreover, the EHG is potentially less sensitive to maternal obesity.

Onderzoeksopzet

An interim analysis will be performed after inclusion of 48 women.

Onderzoeksproduct en/of interventie

Observational diagnostic study of three tocographic methods recorded simultaneously during two hours of labor: 1. electrohysterography (EHG) 2. external tocodynamometry (TOCO) 3. intrauterine pressure catheter (IUPC). Postpartum, we ask women to fill out an evaluation questionnaire regarding patient satisfaction.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria: women with a singleton pregnancy and gestational age between 37 and 42 weeks, in active labor with a fetus in cephalic presentation, ruptured membranes and fetal scalp electrode. We will apply strict criteria regarding diagnosis of labor: a pregnant woman needs to have regular painful contractions at least three each ten minutes, and a fully effaced cervix with minimum 3 centimeters of dilation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation

in this study: women under the age of 18 years old, women with a multiple pregnancy, women with signs of fetal distress (abnormal CTG requiring immediate intervention), women with a positive Group B streptococcus status in urine or vagina, and women with a positive hepatitis B/C or HIV serology. Contraindications to IUPC placement are uterine bleeding of undetermined origin, a suspected placenta praevia, vasa praevia, and signs of intrauterine infection (maternal fever >38C with fetal tachycardia >160 beats per minute). Contraindications to EHG placement are dermatologic diseases of the abdomen precluding preparation of the abdomen with abrasive paper, women in labor taking a shower or bath and women connected to external or implanted electrical stimulators.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Geen controle groep
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	30-07-2014
Aantal proefpersonen:	131
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40734
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5477
NTR-old	NTR5894
CCMO	NL48951.015.14
OMON	NL-OMON40734

Resultaten

Samenvatting resultaten
Not yet