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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23485

Source
Nationaal Trial Register

Brief title
W3-study

Health condition

Uterine contraction monitoring during term labor with three different techniques.

Sponsors and support

Primary sponsor: Board of Management Máxima Medical Center, Veldhoven, the Netherlands
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Both primary study parameters will be evaluated in a sub group of morbidly obese women. And sub analysis will also be performed to compare non-obese and obese, and to compare pregnant women with or without analgesia. Other performance characteristics are: positive predictive value, correlation and contractions consistency index. A Bland-Altman analysis with scatterplot will be carried out to determine the agreement between electrohysterography or external tocodynamometry with intrauterine pressure measurements. Finally, patient preference will be evaluated.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-07-2014
Enrollment:	131
Type:	Actual

Ethics review

Positive opinion

Date:	12-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40734
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
Not yet