Observational study - Monitoring contractions during labor: comparing real-time electrohysterography to external and internal tocodynamometry

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON40734

Source
ToetsingOnline

Brief title
W3-study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Contractions, uterine activity

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Stichting de Weijerhorst. Januari 2012 heeft professor Oei van Stichting de Weijerhorst een donatie van 2.7 miljoen mogen ontvangen ter bevordering van de non-invasieve elektrofoetomaternale bewaking tijdens de bevalling. Dit betreft een samenwerkingsverband tussen het Maxima Medisch Centrum en de Technische Universiteit van Eindhoven;waaronder electrohysterografie. Het doel is om de twee belangrijkste problemen tijdens de bevalling te reduceren: vroeggeboorte en zuurstofgebrek (asfyxie).

Intervention

Keyword: Electrohysterography, External tocodynamometry, Intrauterine pressure catheter, Uterine activity

Outcome measures

Primary outcome

The primary outcome measure will be sensitivity of real-time

electrohysterography to monitor contractions in pregnant women during 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. An interim analysis will be performed after inclusion

of 48 women.

Secondary outcome

Both primary study parameters will be evaluated in morbidly obese women. And

sub analysis will 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

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. An innovative technique to monitor uterine activity, electrohysterography (EHG), is developed and extensively evaluated in a collaboration between University of Technology Eindhoven and Máxima Medical Center. 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 less sensitive to maternal obesity.

Study objective

The main outcome measure is the sensitivity of real-time electrohysterography for detecting contractions, using an intrauterine pressure catheter as reference. Furthermore, the accuracy of EHG will be compared to external tocodynamometry for monitoring contractions during labor. A subset analysis will be performed of morbidly obese women. Another goal is to compare sensitivity of both external methods in pregnant women with or without analgesia, and with or without obesity. Additional secondary outcome will be patient preference.

Study design

Observational diagnostic study of three tocographic methods recorded simultaneously during two hours of labor:
1. real-time electrohysterography (EHG)
2. external tocodynamometry (TOCO)
3. intrauterine pressure catheter (IUPC)
Only the intrauterine pressure output for uterine activity will be displayed at the nurses and obstetricians. Postpartum, we ask women to fill out an evaluation questionnaire regarding patient satisfaction.

Study burden and risks

The investigational electrohysterography and the external tocodynamometer are non-invasive methods to monitor uterine activity during labor. Rare complications have been reported regarding the IUPC, which are thought to be related to improper placement. These include placental damage and uterine wall perforation. No data is available on the incidence of these complications. However, in a recent Cochrane review comparing internal (n=977) and external tocodynamometry (n=968) there were no complications reported from the use of the IUPC. Moreover, the IUPC is still widely used in daily practice in many obstetrical wards in the Netherlands. The protocol for IUPC placement will include ultrasound guided placement to minimize the risk of improper placement. Only midwives, residents and gynecologist that have experience in placing IUPC*s will perform the placement of an IUPC. Unexperienced professionals will need to be trained before using IUPC*s. The questionnaire on patient preference will take less than 10 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 known positive GBS (Group B Streptococcus)-status in the urine or vagina, and women with a positive hepatitis B, hepatitis 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, 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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2014

Enrollment:	131
Type:	Actual

Medical products/devices used

Generic name:	Graphium electrodepatch with PUREtrace module
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-07-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23485
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48951.015.14
OMON	NL-OMON23485