Uterine contractions monitoring using the electrohysterogram.

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To study the validity of the AN24 monitor for uEMG monitoring of uterine contractions compared to intra-uterine pressure monitoring during labour.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of labour and delivery
Study type	Observational non invasive

Summary

ID

NL-OMON33927

Source
ToetsingOnline

Brief title
Uterine Activity Trial

Condition

- Maternal complications of labour and delivery

Synonym
uterine activity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Monica Healthcare Ltd.

Intervention

Keyword: Uterine contractions, Uterine electromyography, Validity

Outcome measures

Primary outcome

The accuracy of uterine contraction monitoring with uEMG in terms of the

sensitivity, positive predictive value, frequency, duration, and amplitude of

the uterine contractions.

Secondary outcome

not applicable

Study description

Background summary

Current techniques for monitoring uterine contractions during labour are either restricted by their performance (tocodynamometry) or are considered invasive (intra uterine pressure catheter; IUPC) and could therefore generate a potential risk for the women in labour. An alternative method uses the uterine electrical activity to quantify contractions. This method (uterine electromyography; uEMG) is not only a surrogate for the existing techniques but might be considered beneficial as it contains new, clinical information on the quality of contractions. The validity of the uEMG technique has been studied before, however only small study-populations, or in non-clinical settings. The objective of the current study is to evaluate the accuracy of AN24 monitor for the monitoring of uterine contractions during labour by comparing with intra-uterine pressure catheter measurements.

Study objective

To study the validity of the AN24 monitor for uEMG monitoring of uterine contractions compared to intra-uterine pressure monitoring during labour.

Study design

Prospective, observational cohort study. Women in early labour receive a 60-minute recording of uterine contractions using five transabdominally placed

electrodes to record the uterine electromyogram (uEMG).

Study burden and risks

The burden is minimal and the risks of this study are to be negligible. Patients will be asked to perform a simultaneous 60-minute measurement of uterine contraction monitoring. The intra uterine pressure catheter (IUPC) is the reference test for uterine contraction monitoring, and has been inserted prior to giving study information to the woman eligible for this study. Uterine contractions will be monitored simultaneously using the uEMG signal with the AN24-monitor (Monica Healthcare, Nottingham). The AN24 has been tested for its use in the clinical setting by the Department of Medical Technology of the UMCU (see appendix of protocol) and has received CE marking for electromyographic recordings of both the fetal- and maternal heart rates, as well as for the registration of uterine contractions (see appendix of protocol). The use of the AN24 monitor presents no risks whatsoever for mother or fetus. It is non-invasive, does not prevent the use of any other diagnostic tools used in current clinical practice and does not restrict the mobility of women in labour.

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

> 18 years of age
Gestational age >37 weeks
Singleton pregnancy
Intra uterine pressure monitoring

Exclusion criteria

Multiple pregancy (twin, triplet)
Fetal malformation/chromosomal abnormalities
Active labour
Bad physical condition

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2009
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL14824.041.08