

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Maternal complications of labour and delivery
<b>Study type</b>	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 pregnancy (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