Monitoring uterine activity and progress of labour using electrohysterography

Published: 06-07-2009
Last updated: 06-05-2024

Investigate whether characteristics of uterine activity during labour measured using EHG are associated with the rate of cervical dilatation.

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

Summary

ID

NL-OMON37278

Source
ToetsingOnline

Brief title
MAPLE

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
dystocia, failure to progress

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, Notthingam, UK

Intervention

Keyword: dystocia, electrohysterography, labour, uterine activity

Outcome measures

Primary outcome

Association of uterine activity characteristics measured using EHG with:

1. duration of stages of labour,

2. incidence of labour stimulation,

Secondary outcome

n.a.

Study description

Background summary

The rate of obstetric interventions has increased significantly in all western countries in the past 20 years. The largest increase is found, in absolute terms, in those pregnancies most likely to deliver vaginally: nullipara at term with singleton in cephalic presentation. About half of these CS are performed because of protracted labour. Eventually, because of repeat CS, failure to progress is thought to account for up to 60% of all CS performed. The diagnosis of protracted labour or labour arrest, however, is not unequivocally defined. A more thorough understanding of the (patho)physiology of labour is clearly required to refine the risk estimation of labour protraction and thus improve the indication for obstetric interventions. Accurate monitoring of labour could play a large role in this process. Recently, a new way of measuring uterine activity based on non-invasive measurement of its electrical activity has been developed. So far, electrohysterograms (EHG) derived by this method seem to correlate well with other measures of uterine activity and could to be able to help predict adequate progression of labour.

Study objective

Investigate whether characteristics of uterine activity during labour measured using EHG are associated with the rate of cervical dilatation.

Study design

Prospective cohort study.

Study burden and risks

The EHG recording apparatus is CE approved and presents no risks whatsoever for mother or child. It is non-invasive, does not prevent the use of any other diagnostic tools used in current clinical practice and does not restraint the mobility of women in labour. In preliminary studies, only minor discomfort due to local irritation under the electrodes has been experienced by participating women.

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

Aged 18 years old or more
In labour (spontaneous or induced)
Nullipara
Singleton pregnancy
Cephalic presentation
at term: >36 weeks of gestation

Exclusion criteria

Known chromosomal and/or structural anomalies in the fetus
Intrauterine fetal death

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):	10-08-2009
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2009
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-06-2011
Application type:	Amendment
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	NL24144.041.08