Evaluation of the effectivity of the electrohysterogram to monitor trial of labour: multicentre randomised controlled trial.

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To evaluate the effectivity of the electrohysterogram (EHG) by means of a tocopatch electrode compared to tocodynamometry by means of an external tocodynamometer or intrauterine pressure catheter (IUPC) to monitor trial of labour (TOL) in patients...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON35744

Source
ToetsingOnline

Brief title
Tocopatch

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
trial of labour

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Co-financiering Máxima Medisch Centrum en NEMO Healthcare BV toegekend; aanvraag Zon/Mw ingediend,NEMO Healthcare BV

Intervention

Keyword: electrohysterogram, tocodynamometry, trial of labour, vaginal birth after caesarean

Outcome measures

Primary outcome

Number of succesful trials of labour

Secondary outcome

Admittance to NICU

perinatal mortality

maternal morbidity

costs

Study description

Background summary

Avoiding the morbidity of repeat caesarean section through vaginal birth after caesarean (VBAC) is an attractive option in a majority of women. Moreover the costs of a vaginal birth are much less than the costs of a caesarean section. However, the success rate of TOL is low. Tocodynamometry is currently used as monitoring technique. The test properties of tocodynamometry are poor and the technique is invasive (IUPC). An innovative technique, electrohysterography (EHG), is developed and extensively evaluated in a collaboration between TU/e and MMC. The advantage of EHG is that it is non-invasive, accurate, and applicable on a continuous basis.

Study objective

To evaluate the effectivity of the electrohysterogram (EHG) by means of a tocopatch electrode compared to tocodynamometry by means of an external tocodynamometer or intrauterine pressure catheter (IUPC) to monitor trial of labour (TOL) in patients with one previous caesarean section (c.section) in

order to increase the VBAC rate without increasing the risk of uterine rupture.

Study design

Multicentre randomised clinical trial

Study burden and risks

The tocopatch is a non-invasive method, from which minimal risks are expected. The extent of the burden associated with participation is minimal. It is necesarry to use this population for this study, because of the objects of this study.

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

Prior caesarean sectio
Singleton pregnancy

Exclusion criteria

previous uterine rupture
intrauterine fetal death
breech presentation
2 or more prior caesarean sections
multiple pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	548
Type:	Actual

Ethics review

Approved WMO

Date:	20-05-2011
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

No registrations found.

In other registers

Register	ID
CCMO	NL36116.015.11