

# **\*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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Pregnancy, labour, delivery and postpartum conditions
<b>Study type</b>	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 necessary 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 section  
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

## 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