# SIMPLE III; a randomised controlled noninferiority trial: best timing for a caesarean section in non-progressing labour;

Published: 04-07-2016 Last updated: 19-04-2024

To compare the currently used Friedman partogram (FP) to the newly developed SIMPLE partogram (SP), based on the normogram of the consortium on Safe Labor, for the diagnosis and treatment of non-progressing labour.

**Ethical review** Approved WMO

**Status** Recruitment stopped

**Health condition type** Pregnancy, labour, delivery and postpartum conditions

Study type Interventional

### **Summary**

#### ID

NL-OMON46322

#### **Source**

ToetsingOnline

#### **Brief title**

SIMPLE III

### **Condition**

• Pregnancy, labour, delivery and postpartum conditions

#### Synonym

non-progressing labour; labour arrest

### **Research involving**

Human

### **Sponsors and support**

Primary sponsor: Obstetrie & Gynaecologie

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Source(s) of monetary or material Support: ZonMw

Intervention

**Keyword:** caesarean section, expective management, morbidity, non-progressing labour

**Outcome measures** 

**Primary outcome** 

Primary outcome will be mortality and composite severe morbidity (maternal intensive care admittance, Apgar score <7 after 5 minutes, pH <7.10, neonatal intensive care admittance).

**Secondary outcome** 

Secondary outcome will be the mode of delivery, shoulder dystocia, anal sphincter lesion, duration of admission to the hospital, blood loss, need for blood transfusion and maternal- and neonatal infection. Also the total number of caesarean sections in the target population (including non-participating women) will be analysed. Furthermore, cost effectiveness, budget impact, patient preference and patient satisfaction will be part of the secondary outcome.

# **Study description**

#### **Background summary**

A caesarean section performed without a clear indication results in additional morbidity and costs without improvement of outcome. The group of women delivering their first baby is the largest contributor to the caesarean section rate (31% of all caesarean sections in the Netherlands, 10.000 annually). In about 11% of all deliveries in second line care, women are diagnosed with non-progressing labour, resulting in a caesarean section in 45% (SIMPLE I). This makes non-progressing labour one of the most important indications for a caesarean section. Although in the Netherlands about 6400 caesarean sections

are annually performed based on non-progressing labour, the actual moment of diagnosis and timing of the caesarean section in this group is still unclear. The second largest group contributing to the caesarean section rate are women with a previous caesarean section. Reducing the number of caesarean sections in the first pregnancy reduces the number in the following one by at least 50%.

### Study objective

To compare the currently used Friedman partogram (FP) to the newly developed SIMPLE partogram (SP), based on the normogram of the consortium on Safe Labor, for the diagnosis and treatment of non-progressing labour.

### Study design

Multi-centre randomised controlled trial

#### Intervention

When after regular interventions (rupture of membranes, adequate pain medication, oxytocin augmentation, empty bladder) the Friedman partogram is crossed, randomisation occurs between performing a caesarean section (control group) and waiting until the Simple partogram action line is crossed (intervention group).

### Study burden and risks

The control group receives care as usual (caesarean section when the Friedman partogram action line is crossed), with no additional risks. Waiting until the Simple partogram action line is crossed (intervention group) might give a higher composite morbidity rate, which will be the main study outcome. No additional medication or blood samples will be taken. Nor will there be extra visits. Patients will be asked to fill in a questionnaire to measure patient satisfaction.

### **Contacts**

### **Public**

Selecteer

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#### Scientific

Selecteer

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### **Trial sites**

### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

### Age

Adults (18-64 years) Elderly (65 years and older)

### Inclusion criteria

Nulliparous
Singleton pregnancy
Cephalic presentation

- \* 37 weeks of pregnancy
- \* 4 cm dilatation

Non-progressing labour (passing the Friedman partogram action line) Pain considered manageable for continuation of delivery

### **Exclusion criteria**

< 18 years of age
Unable to read or understand informed consent
Fetus with relevant congenital malformation that can influence the delivery
mode OR have a higher risk of NICU admittance
Indication for a caesarean section due to fetal distress

# Study design

### **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-01-2017

Enrollment: 2388

Type: Actual

## **Ethics review**

Approved WMO

Date: 04-07-2016

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 09-11-2016

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 01-03-2017

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

# **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 NL55102.068.15

# **Study results**

Date completed: 18-08-2017

Actual enrolment: 4

**Summary results** 

Trial ended prematurely