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

Published: 04-07-2016
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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

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

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Selecteer

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Scientific
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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