Best timing of a cesarean section in non-progressing labour

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26046

Source
Nationaal Trial Register

Brief title
SIMPLE III

Health condition

Non-progressing labour (niet vorderende ontsluiting)
Diagnosis (diagnose)
Cesarean section (keizersnede)
Morbidity (morbiditeit)

Sponsors and support

Primary sponsor: Maastricht University Medical Centre +
NVOG Consortium 2.0
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Mortality and composite morbidity: maternal IC admittance, Apgar score <7 after 5 minutes,

pH <7.10, NICU admittance.

Secondary outcome

Delivery mode, Shoulder dystocia, Anal sphincter lesions, Blood loss, Need for blood transfusion, Maternal infection, Neonatal infection, Duration of admission to the hospital, Total number of caesarean sections in the target population (including non participating women). Furthermore cost evaluation, budget impact, patient preference and patient satisfaction.

Study description

Background summary

RATIONALE

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%.

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

STUDY POPULATION

Term nulliparous women with a singleton pregnancy and a child in cephalic presentation.

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).

MAIN STUDY PARAMETERS/ENDPOINTS

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 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 objective

A cesarean section performed without a clear indication results in additional morbidity and costs without improvement of outcome. The group of women delivering their first baby in cephalic presentation at term is the largest contributor to the caesarean section rate. In about 11% of all deliveries, women are diagnosed with non-progressing labour resulting in a caesarean section in 45% (SIMPLE I study), making it one of the most important indications for a cesarean section. Although in the Netherlands about 6400 cesarean sections are annually performed based on non-progressing labour, with 30 million euro in direct costs only, the actual moment of diagnosis and timing of a cesarean for this indication is still unclear. The second largest group contributing to the cesarean section rate are women with a previous cesarean section. Reducing the number of cesarean sections in the first pregnancy, reduces the number in the consecutive one by at least 50%. Normal duration of delivery is described in a nomogram with an action line of deviation resulting in a partogram that dictates at what point action should follow. The currently used partogram by Friedman with a four hour action line is based on a small dataset of women of more than 50 years ago. Recently the Consortium on Safe Labor has revised the cartogram based on more than 60.000 women in labour who delivered vaginally with favorable neonatal outcome. This

nomogram showed that labour with normal outcome in most cases is longer than was previously assumed. Currently, intervention occurs when the Friedman action line is crossed after all regular measures have been taken. This results in early intervention and even possible a cesarean section that is performed too early than necessary.

Study design

6 months follow-up from baseline (delivery).

- Discrete choice experiment to measure patient preference (300 patients) : 6 and 12 weeks of follow up.

- Cost questionnaire (300 patients): baseline, 3 and 6 months of follow up.

- Health related quality will be measured using the EQ-5D (300 patients): baseline, 7 days, 3 and 6 months of follow up.

- Patient satisfaction questionnaire in the first week after delivery

Intervention

When after all regular interventions for non-progressing labour (amniotomy, oxytocin augmentation, empty bladder, pain medication) the Friedman partogram action line is crossed, randomization occurs in which performing a cesarean section is the regular conduct. In women in the intervention group is waited until the Simple cartogram action line is crossed (based on the 95th percentile of the nomogram of the Consortium on Safe Labor).

Contacts

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Eligibility criteria

Inclusion criteria

Nulliparous

Singleton pregnancy

Cephalic presentation

≥ 37 weeks of pregnancy

≥ 4 cm dilatation

Non-progressing labour (<1cm/hour)

Exclusion criteria

< 18 years of age

Unable to read or understand informed consent

Fetus with relevant congenital malformation

Planned caesarean section

Non reassuring fetal condition

Inadequate pain medication (as judged by the women herself, no absolute need for epidural, but pain needs to be considered manageable for continuation of delivery)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2015
Enrollment:	2388
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5253
NTR-old	NTR5543

Register	ID
Other	ZonMw : 80-84300-98-63004

Study results