Best timing of a cesarean section in non-progressing labour

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26046

Bron
NTR

Verkorte titel
SIMPLE III

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre +
NVOG Consortium 2.0
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mortality and composite morbidity: maternal IC admittance, Apgar score <7 after 5 minutes, pH <7.10, NICU admittance.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Nulliparous

Singleton pregnancy

Cephalic presentation

≥ 37 weeks of pregnancy

≥ 4 cm dilatation

Non-progressing labour (<1cm/hour)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

< 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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	2388
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5253
NTR-old	NTR5543

Register	ID
Ander register	ZonMw : 80-84300-98-63004

Resultaten