

Effectiveness of fetal scalp blood sampling for the prevention of cesarean section in case of suspected fetal distress during labor

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Consistent application of FBS in the first stage of labor, reduces the Cesarean section (CS) rate in case of suspected fetal distress with at least 15%.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28995

Bron

Nationaal Trial Register

Verkorte titel

SCALP

Aandoening

Fetal distress during labor , fetal acidosis, foetale nood,

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Center

Overige ondersteuning: ZonMw grant application 80-83700-98-42010

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cesarean section.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE(S)/RESEARCH QUESTION(S):

Is fetal scalp blood sampling (FBS) cost-effective in preventing unnecessary cesarean section (CS) in case of suspected fetal distress during labor?

HYPOTHESIS:

Applying FBS consistently in the first stage of labor, reduces the CS rate in case of suspected fetal distress with at least 15%,
without a negative impact on perinatal outcome.

STUDY DESIGN:

Multicenter RCT embedded in cohort with informed consent during pregnancy and randomization in case of an abnormal cardiotocogram (CTG) during labor.

STUDY POPULATION(S)/DATASETS:

Women with a singleton pregnancy of 36 weeks or over with an indication for continuous CTG monitoring are included in the cohort. When fetal distress is suspected during the first stage of labor women are randomized for either FBS or no-FBS.

INTERVENTIONS:

In case of suspected fetal distress, randomization for decision making using FBS (intervention) or decision making using CTG only (control).

PRIMARY OUTCOME MEASURE:

Cesarean Section.

SECONDARY OUTCOME MEASURE:

Composite poor perinatal outcome, maternal complications, women's birth experience.

SAMPLE SIZE CALCULATION/DATA ANALYSIS:

In the Netherlands, two types of fetal monitoring are used; CTG with and without ST-analysis of the fetal electrocardiogram (STAN). In order to show superiority of a strategy with FBS:

1. In CTG WITHOUT STAN, 2 groups of 140 women are needed. This number is sufficient to show a reduction in CS rate of at least 15% (from 80% to 65%)(two sided test; alpha 0.05, beta 0.02);
2. In CTG WITH STAN, 2 groups of 60 women are needed to show a similar reduction in CS rate (from 95% to 80%) (one sided test; alpha 0.05, beta 0.02). Analysis will follow the intention to treat principle. Treatment effect will be described as relative risk with 95% confidence intervals.

COST-EFFECTIVENESS ANALYSIS/ BUDGET IMPACT ANALYSIS:

A cost-effectiveness analysis of the two strategies, FBS or no FBS, will be performed. alongside the clinical trial.

Doel van het onderzoek

Consistent application of FBS in the first stage of labor, reduces the Cesarean section (CS) rate in case of suspected fetal distress with at least 15%.

Onderzoeksopzet

Eligible women are included in the cohort at a gestational age of 34 weeks. Baseline characteristics are then recorded. Randomization is performed during labor when fetal distress is suspected. Women's birth experiences are measured after 24 hours post partum. For the cost effectiveness analysis follow-up is up to 6 weeks post partum.

Onderzoeksproduct en/of interventie

The Scalp trial is a multicenter RCT embedded in cohort with informed consent during pregnancy and randomization in case of an abnormal CTG during labor.

Our design entails a stratified randomization for fetal surveillance method, CTG with, or without STAN.

Only if and when the CTG has become abnormal, women will be randomly assigned to either FBS (intervention group) or no FBS, i.e. management based on CTG only (control group).

In women allocated to the intervention group FBS is performed according the standard technique and local protocol. Further management is then based on CTG and FBS results.

In women allocated to the control group no FBS is performed but management is based on CTG only. Delivery is expedited at the discretion of the consultant obstetrician. In case of STAN use, allocation to the control group means immediate CS.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria cohort:

1. Informed consent before the beginning of labor;
2. Working knowledge of Dutch language;
3. Singleton fetus in vertex position;
4. Gestational age 36.0 weeks or over.

Inclusion criteria RCT:

1. First stage of labor (i.e. dilatation > 2 cm and/or presenting part > Hodge 1);
2. Abnormal cardiotocogram (CTG) or abnormal ST analysis of the fetal ECG (STAN).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria cohort:

1. Major congenital anomalies;
2. Contraindications for fetal scalp blood sampling (e.g. HIV, hemophilia);
3. Previous CS.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37995
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3653
NTR-old	NTR3837
CCMO	NL37344.091.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37995

Resultaten

Samenvatting resultaten

N/A