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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28995

**Source**
Nationaal Trial Register

**Brief title**
SCALP

**Health condition**

Fetal distress during labor , fetal acidosis, foetale nood,

### Sponsors and support

**Primary sponsor:** Radboud University Nijmegen Medical Center
**Source(s) of monetary or material Support:** ZonMw grant application 80-83700-98-42010

### Intervention

### Outcome measures

**Primary outcome**

Cesarean section.

**Secondary outcome**

1. Composite poor perinatal outcome, which includes: Metabolic acidosis at birth (umbilical artery pH < 7.05 + base deficit (full blood) > 12 mmol/l, Severe acidosis at birth (umbilical artery pH < 7.00), Five minute Apgar score < 7, Evidence of hypoxic ischemic encephalopathy (Sarnat stage 2 or 3), Perinatal death during delivery or within 28 days after birth;

2. Maternal complications;

3. Women's birth experiences.

A cost effectiveness and budget impact analysis is performed alongside the clinical trial.

# Study description

**Background summary**

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.

SECUNDARY 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. allongside the clinical trial.

**Study objective**

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%.

**Study design**

Eligble 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.

**Intervention**

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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).

### Exclusion criteria

Exclusion criteria cohort:

1. Major congenital anomalies;

2. Contraindications for fetal scalp blood sampling (e.g. HIV, hemophilia);

3. Previous CS.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-03-2013 |
| Enrollment: | 400 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 04-02-2013 |
| Application type: | First submission |

## Study registrations

## Followed up by the following (possibly more current) registration

ID: 37995
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

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

# Study results

**Summary results**
N/A