# Effectiveness of fetal scalp blood sampling for the prevention of cesarean section in case of suspected fetal distress during labor (SCALP-trial); a randomized controlled multicenter study

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The primary aim of this study is to determine to what extent FBS is effective in preventing unnecessary operative delivery for CTG-suspected fetal distress. The secondary aims are to determine if FBS does not enhance poor perinatal outcome. Tertiary…

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Pregnancy, labour, delivery and postpartum conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37995

**Source**
ToetsingOnline

**Brief title**
Scalp trial

### Condition

- Pregnancy, labour, delivery and postpartum conditions

**Synonym**
fetal asphyxia, fetal compromise, fetal distress

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cardiotocography, cesarean section, fetal distress, fetal scalp blood sampling

## Outcome measures

### Primary outcome

The primary outcome is the CS rate for all indications.

### Secondary outcome

Secondary outcome is a composite of poor neonatal outcome including:

Neonatal metabolic acidosis (umbilical artery pH < 7.05 + base deficit (full blood) > 12 mmol/l);

Severe neonatal acidosis ( umbilical artery pH < 7.00);

Five minute Apgar score < 7;

Neonatal death within 28 days;

Evidence of hypoxic ischemic encephalopathy (Sarnat stage 2 or 3).

Maternal secondary outcome variables include mode of delivery and blood loss during delivery.

Also cost and effects are measured as well as patient reported outcomes. See protocol page 22.

# Study description

**Background summary**

Continuous cardiotocography (CTG) is used in the majority of pregnancies to monitor fetal wellbeing. The method is associated with an increase in cesarean sections (CS) without an improvement in long-term perinatal outcome(1). CS is associated with a 4 fold higher risk of maternal mortality and severe morbidity compared to a vaginal birth. Moreover a CS in the previous pregnancy carries a risk of serious complications in the subsequent pregnancy.

In order to avoid unnecessary operative delivery in case of suspected fetal distress, fetal blood sampling (FBS) can be used as an adjunctive test to CTG. It is a procedure whereby a small amount of blood is taken from the fetal scalp, to measure acid-base balance (pH, base deficit). FBS has been introduced in the 1960's in an effort to identify those babies who are truly compromised and need to be born immediately and to differentiate them from those who are not truly compromised. There is limited evidence to support this assumption. In a meta analysis of randomized comparisons between CTG and intermittend auscultation during labor, it was shown that CTG increases the CS rate (OR 1.96, 95% CI 1.24-3.09). If FBS was applied to CTG this rise in CS appeared to be less profound (OR 1.50, 95% CI 1.10-2.06).

CTG abnormalities occur rather frequently with an incidence of 30% during the first stage of labor rising up to 90% during the second stage. The use of FBS in the Netherlands varies widely across hospitals. A national survey (2008) showed that all of the larger (teaching) hospitals use FBS, in approximately 14% of deliveries, whereas the non-teaching hospitals use FBS in only 3% of deliveries.

FBS has been abandoned in the USA. This change in practice was claimed not to be accompanied by an increase in CS rate for suspected fetal distress or in indicators of perinatal asphyxia. However, in the USA FBS was already used rather infrequently (0,5% to 2%), and the CS rate was and is quite high. European guidelines do recommend the use of FBS, assuming it to prevent unnecessary operative delivery despite the fact that its effectiveness is unproven.

FBS is an invasive and cumbersome procedure with high failure rates (up to 20%). Moreover the FBS result only represents a moment in time and the test often has to be repeated. Lactate analysis in FBS, instead of pH largely overcomes these problems, but this has not translated into differences in mode of birth or neonatal outcome. Complications caused by FBS occur with an incidence of 0.4 -6%. The majority of these complications consists of fetal bleeding and infection and seldom results in serious consequences for the

neonate.

Another adjunctive test to CTG is ST analysis of the fetal electrocardiogram (STAN). This technique detects changes in the ST segment of the fetal ECG (ST events), which are related to fetal hypoxia. The occurrence of these ST events are interpreted together with CTG. One third of Dutch delivery wards already uses this method and it is expected that in the near future this will further increase to 50%. Meta analysis shows that STAN use lowers the FBS rate (RR 0*59, 95% CI 0*44-0*79)(11). However, it is still unclear if STAN makes FBS redundant or not.

In the Netherlands approximately 25% of all CS during labor in term singleton pregnancies is performed because of fetal distress (Perinatale Registratie Nederland). This accounts for 3200 cases per year. If this study shows that FBS leads to a reduction in CS of at least 10%, without a negative influence on perinatal outcome, more than 320 CS could be prevented each year, thereby improving maternal health and safety as well as reducing direct delivery costs. If this study shows that FBS is not effective, the method can be abandoned. Either way the results of this study will have great impact on obstetric management in Europe and the USA; abolish or apply FBS consistently.

**Study objective**

The primary aim of this study is to determine to what extent FBS is effective in preventing unnecessary operative delivery for CTG-suspected fetal distress. The secondary aims are to determine if FBS does not enhance poor perinatal outcome. Tertiary objectives include the cost effectiveness and patients experiences.

**Study design**

We propose an observational cohort study in women with continuous CTG monitoring during labor, with randomization of women with CTG suspected fetal distress (i.e. an abnormal CTG).
Eligible women will receive the patient study information at around 34 weeks of gestation, in the outpatient clinic or the ward. After consent, women are included in the study.
Included women will be monitored with continuous CTG with or without ST analysis if the fetal ECG (STAN) during labor. The CTG is classified according to the criteria of the International Federation of Gynecology and Obstetrics modified for ST analysis (FIGO/STAN criteria). CTG patterns are classified as normal, Intermediary, abnormal or pre-terminal.

ONLY if and when the CTG is classified as abnormal randomization is performed through a computer generated sequence. Women are allocated to either FBS with action based on its results (continue monitoring, repeat FBS or immediate

delivery) or no FBS (immediate delivery). See flowchart protocol appendix A.

**Intervention**

The intervention (standard practice in teaching hospitals) is FBS in case of an abnormal CTG (FIGO/STAN criteria) with further action based on its results according to the following guidelines:

pH < 7,20: Abnormal, CS
pH 7,20-7,25: Borderline, repeat FBS * 30 minutes
pH > 7,25: Normal, continue fetal monitoring CTG/STAN, repeat FBS at the discretion of the doctor.

With lactate analysis is FBS other cut-offs are used depending on the lactate meter. See protocol page 18.

**Study burden and risks**

The burden for the women involved in this study is limited to taking note of the background of fetal surveillance during labor, the equipoise of both study-arms and a 18-item questionnaire which has to be filled out shortly after the delivery.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- Singleton fetus in vertex position
- Gestational age * 36.0 weeks
- Absence of contraindications for fetal scalp blood sampling (e.g. HIV, hemophilia)
- First stage of labor (e.g. dilatation > 2 cm and/or presenting part > Hodge 1)
- Abnormal CTG (FIGO/STAN criteria)
- Absence of acute fetal compromise (e.g. pre terminal CTG)

### Exclusion criteria

Major congenital anomalies

## Study design

### Design

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

**Primary purpose:** Diagnostic

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 230 |

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| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 06-12-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 11-04-2013 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

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

No registrations found.

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

ID: 28995
Source: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL37344.091.12 |
| OMON | NL-OMON28995 |