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# The cost-effectiveness of ST-ANalysis of the foetal electrocardiogram as compared to Foetal Blood Sampling for intrapartum monitoring: a randomised controlled trial

**Submission date**
20/12/2005

**Recruitment status**
No longer recruiting

**Registration date**
20/12/2005

**Overall study status**
Completed

**Last Edited**
13/10/2014

**Condition category**
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
NTR174

# Study information

### Scientific Title

### Acronym
STAN versus CTG + FBS

### Study objectives
Cardiotocography (CTG) is worldwide the method for foetal surveillance during labour. However, CTG alone shows many false positive results and without foetal blood sampling (FBS) it results in an increase in operative deliveries without an improvement of foetal outcome. FBS requires additional expertise, is invasive and has often to be repeated during labour. Two randomised controlled trials have shown that a combination of CTG and non-invasive ST-analysis (of the foetal electrocardiogram [ECG]) reduces the rates of metabolic acidosis and instrumental delivery. However, in both randomised controlled trials FBS was still performed in both arms, and it is therefore still unknown if the observed results were indeed due to the ST-analysis or to the use of FBS in combination with ST-analysis.

Hypothesis:
Intrapartum foetal monitoring with the STAN-method (cardiotocograpy with ST-analysis of the foetal ECG) results in less neonates with metabolic acidosis and less interventions for foetal distress as compared to monitoring with cardiotocography in combination with foetal blood sampling.

As of 16/07/2007 the power calculation was changed, and the target number of participants was increased from 2400 to 5100; see interventions section for more details.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethics Committee University Medical Centre Utrecht, 17/11/2005, ref: 05/157-K

### Study design
Randomised active controlled parallel-group multicentre trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)

Screening

## Participant information sheet

## Health condition(s) or problem(s) studied
Women in labour with a high-risk pregnancy

## Interventions
Women will be randomly assigned to routine care including foetal monitoring by cardiotocography with foetal blood sampling (CTG + FBS group) or to the index group including cardiotocography with ST-analysis (CTG + ST group). Clinical management in the CTG + FBS group (routine care) will be guided by guidelines produced by the International Federation of Gynaecology and Obstetrics (FIGO). FBS is recommended in case of a suboptimal or abnormal CTG pattern. In cases with scalp blood pH lower than 7.20 or preterminal cardiotocograms delivery is recommended. In the CTG + ST group, clinical management will be supported by computerised ST waveform assessment and will be guided by the STAN-guidelines, indicating when intervention is recommended. In case of poor signal quality of the foetal ECG-signal it is allowed to perform a FBS in the first stage of labour. From each woman, we will systematically (by protocol) document demographics and medical history, as well as CTG analysis, foetal ST-analysis and FBS results. Finally, the umbilical cord artery results, the performance of an instrumental delivery and neonatal outcome until discharge from the hospital will be documented.

CTG and FBS:
In women randomised to the control group, a scalp electrode will be applied to the foetal head and connected to the conventional CTG-monitor conform routine practice of CTG monitoring. If the pH of the first measurement is below 7,20 delivery is recommended unless the cause of foetal distress can be alleviated. If the pH is between 7,20 and 7,25 FBS will be repeated after 30 minutes. If the pH is above 7,25 FBS is repeated according to CTG pattern according to the attending doctor or midwife. The number of failed FBS will be recorded.

CTG and ST-analysis:
In women randomised to the index group, a scalp electrode will be applied to the foetal head and connected to the STAN-monitor conform routine practice of CTG monitoring. This electrode will allow both standard foetal heart rate monitoring (CTG) as well as ST-analysis. The CTG will be classified as normal, intermediate, abnormal or preterminal according to the FIGO-guidelines for foetal heart rate monitoring. The ST log automatically alerts the attending doctor or midwife if a significant ST-event occurs. Delivery is recommended when there are significant ST-changes unless the cause of foetal distress can be alleviated. It is only allowed to perform FBS in the CTG + ST-analysis arm in case of poor signal quality of the foetal ECG in combination with an intermediate or abnormal foetal heart rate pattern in the first stage.

Power calculation information added as of 16/07/2007:
The sample size calculation is based on the primary endpoint, which is metabolic acidosis in the umbilical cord artery.

Although in the two randomised trials the incidence of metabolic acidosis decreased from 1.5% to 0.5% in favour of the CTG + ST-analysis group, we assume that the incidence of metabolic acidosis in our higher-risk population (women delivering in the hospital with a medical indication) is higher and estimated on 3.5%, as found in our preliminary study. Based upon the numbers of the largest clinical trial with a relative risk of 0.5 the required sample size would then yield 2400 cases (1200 per arm), using an alpha of 0.05 (2-sided) and a power of 0.80.

However, soon after the start of our study a third randomised clinical trial appeared, although much smaller and non-significant, but yielding an opposite effect . A meta-analysis of the three clinical trials showed the varying relative risks of 0.5, 0.4 and 2.4. Hence, to be conservative we used the meta-analysis overall relative risk of 0.6 for our power calculation, implying a reduction of metabolic acidosis, in favour of ST-analysis, from 3.5% to 2.1%. With an alpha of 0.05, a two-sided test (given conflicting results in the literature) and a power of 0.80, about 4638 women should be randomised (2319 per arm). Accounting for 10% loss to follow-up, the study requires inclusion of about 5100 women in order to obtain 4638 analysable cases.

As of 06/01/2009 this record was amended to include the following information: The inclusion of participants for this trial is complete.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Presence or absence of metabolic acidosis defined as a pH less than 7.05 and a BDecf greater than 12 mmol/l in the umbilical cord artery.

There are no interim analyses, only by the data safety monitorings committee for serious adverse events.

### Secondary outcome measures
1. Instrumental delivery rate for the following indications: foetal distress, failure to progress or a combination of these
2. Cost-effectiveness of both strategies: the ratio of incremental costs and the reduced rate of metabolic acidosis, associated with the strategies
3. Neonatal outcome defined by low Apgar scores, defined as less than four after one minute and /or less than seven after five minutes
4. Need for admission to the neonatal medium or intensive care unit
5. Cost-effectiveness of both monitoring strategies across hospitals, particularly, comparing academic and non-academic hospitals

There are no interim analyses, only by the data safety monitorings committee for serious adverse events.

### Overall study start date
01/04/2006

### Completion date
01/04/2009

## Eligibility

### Key inclusion criteria

1. Women in labour
2. Singleton foetus in vertex position
3. Gestational age more than 35 + 6 weeks of gestation
4. Indication for electronic foetal monitoring (CTG)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
5100

### Key exclusion criteria
1. Women with a foetus in breech position
2. Women with twin pregnancy
3. No informed consent

### Date of first enrolment
01/04/2006

### Date of final enrolment
01/04/2009

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**University Medical Centre Utrecht**
Utrecht
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## Sponsor information

### Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

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### Sponsor type
University/education

### Website
http://www.umcutrecht.nl/zorg/

### ROR
https://ror.org/04pp8hn57

## Funder(s)

### Funder type
Research organisation

### Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 26/07/2007 | | Yes | No |
| Results article | results | 01/06/2010 | | Yes | No |
| Results article | results | 01/07/2012 | | Yes | No |