The cost-effectiveness of ST-analysis of the fetal electrocardiogram as compared to fetal blood sampling for intrapartum monitoring: a randomised controlled trial.

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

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

Samenvatting

ID

NL-OMON25863

Bron
NTR

Verkorte titel
STAN versus CTG + FBS

Aandoening

women in labour with a high-risk pregnancy

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht, the Netherlands
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Presence or absence of metabolic acidosis defined as a pH < 7.05 and a BDecf > 12 mmol/l in the umbilical cord artery.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Cardiotocography (CTG) is worldwide the method for fetal surveillance during labour. However, CTG alone shows many false positive results and without fetal blood sampling (FBS) it results in an increase in operative deliveries without an improvement of fetal outcome. FBS requires additional expertise, is invasive and has often to be repeated during labour. Two RCTs have shown that a combination of CTG and non-invasive ST-analysis (of the fetal ECG) reduces the rates of metabolic acidosis and instrumental delivery. However, in both RCTs 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.

Objective:
To quantify costs and effectiveness of non-invasive monitoring (CTG + ST-analysis) as compared to normal care (CTG + FBS), in order to judge whether the ST-analysis can replace FBS.

Study design:
Multicentre randomised controlled trial in eight hospitals.

Study population:
Women in labour (> 36 weeks of gestation) with an indication for CTG.
Interventions:
Women will be randomised for fetal surveillance with CTG + FBS or CTG + ST-analysis.

Outcome measures:
Primary outcome is the incidence of metabolic acidosis (defined as pH < 7.05 and BDecf > 12 mmol/l in the umbilical cord artery).
Secondary outcome measures are:
instrumental delivery rate, cost-effectiveness, neonatal outcome (Apgar score, admission to a neonatal ward) and cost-effectiveness of both monitoring strategies across hospitals.

Power/data analysis:
The analysis will follow the intention to treat principle. The incidence of metabolic acidosis will be compared across both groups. Assuming a reduction of metabolic acidosis from 3.5 to

2.1%, using a two sided test with an alpha of 0.05 and a beta of 0.80, in favour of CTG + ST-analysis, 5100 women have to be randomised (2550 per group).

Economic evaluation:
The economic evaluation is designed as cost-effectiveness analysis, i.e. the ratio of (I) incremental costs and (II) the reduced rate of metabolic acidosis, associated with the strategies is quantified.

Time Schedule:
The total research period is 3 years: a start-up phase of 4 months, an inclusion period of 26 months and 6 months to realise follow-up, analysis and reporting.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

Women will be randomly assigned to routine care including fetal monitoring by cardiotocography with fetal 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 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 fetal 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, fetal ST-analyis 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 fetal 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 fetal 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 fetal head and connected to the STAN-monitor conform routine practice of CTG monitoring. This electrode will allow both standard fetal 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 fetal 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 (see appendix B) unless the cause of fetal 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 fetal ECG in combination with an intermediate or abnormal fetal heart rate pattern in the first stage.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women in labour with a singleton fetus in vertex position and a gestational age > 35 + 6 weeks of gestation and an indication for electronic fetal monitoring (CTG).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women with a fetus in breech position;

2. Women with twin pregnancy;

3. No informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	5100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2005
Soort:	Eerste indiening

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	NL139
NTR-old	NTR174
Ander register	: N/A
ISRCTN	ISRCTN95732366

Resultaten

Samenvatting resultaten
N/A