Intrapartum monitoring: a prospective observational cohort

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These women will act as a control group for an implementation study for the non-invasive fetal ECG, which will be performed later this year.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25099

Bron
Nationaal Trial Register

Verkorte titel
Intrapartum monitoring: a prospective observational cohort

Aandoening

Every patient who delivers at our clinic

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main goal of this prospective observational study is to collect data to record maternal and neonatal outcomes of fetal monitoring during labour by using the conventional CTG (DU or FSE and TOCO). The collected data will be control data for an implementation study for the

NI-fECG, which will be performed later this year.

Maternal outcomes: episiotomy and its indication, spontaneous vaginal deliveries and operative deliveries (vacuum extractions or caesarean section) with indication (fetal distress and/or failure to progress).
Neonatal outcomes: FBS during delivery, birth weight, gender, Apgar score, admission to a neonatal ward, pH in umbilical artery and vein.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: There are two possibilities for non-invasive fetal monitoring: the conventional cardiotocogram (CTG) using Doppler ultrasound (DU) for the fetal heart rate (FHR) and external tocography (TOCO) for uterine contractions or the non-invasive fetal electrocardiography (NI-fECG) using electrical waveforms of the fetal heart to register FHR and electrohysterography (EHG) for uterine contractions. Currently the conventional CTG is used for fetal monitoring during labour.
Objective: The aim of this study is to prospectively collect data to record maternal and neonatal outcomes of fetal monitoring during labour by using the conventional CTG.
Study design: This is a multi-center prospective observational cohort study.
Study population: Pregnant women with fetal monitoring during delivery, carrying at least one living fetus. These women will act as a control group for an implementation study for the NI-fECG, which will be performed later this year. After inclusion of the first 200 women, we continue to include women as part of a large prospective observational multicenter cohort on fetal monitoring during labor and obstetrical outcomes. This study serves as an important step towards prospective observational collection of data concerning monitoring during delivery on a larger scale. In addition, big data will provide reliable results concerning outcomes of obstetrical care in different subgroups in secondary and tertiary obstetric clinics.
Intervention (if applicable): Standard care. All women during delivery will receive transducers placed on the abdomen: one above the fetal heart to monitor FHR (DU) and the other at the fundus of the uterus (TOCO) to measure frequency of contractions. A FSE is placed when the membranes are ruptured and FHR monitoring is insufficient by using DU. To obtain complementary fetal information during labor, FBS can be needed and performed.
Main study parameters/endpoints: The primary outcomes are maternal and neonatal outcomes. Maternal outcomes: the percentage of episiotomy and its indication, the percentage of episiotomy and its indication, spontaneous vaginal deliveries, the percentage and indications of operative deliveries (vacuum extractions or caesarean section). Neonatal outcomes: percentage of FBS during delivery, gender, birth weight (dysmaturity and macrosomia), admission to neonatal ward with reason, Apgar score (<7 after 5 minutes), pH in umbilical artery and vein, severe metabolic acidosis (pH < 7.00 and base deficit ≥ 12 mmol/L). Secondary outcomes are the percentage of FSE that was used and how often FBS was performed. Complications during delivery: shoulder dystocia, intrapartum maternal fever, eclampsia, postpartum hemorrhage, thrombosis, wound infection, endometritis,

mastitis.

Doel van het onderzoek

These women will act as a control group for an implementation study for the non-invasive fetal ECG, which will be performed later this year.

Onderzoeksopzet

Standard care until 6 weeks postpartum

Onderzoeksproduct en/of interventie

None, standard care

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria: pregnant women who are admitted to the labor ward because of (induction of) labor or postpartum women who delivered at the labor ward with fetal monitoring during delivery, carrying at least one living fetus. Patients are only included after oral and written informed

consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None, monitoring standard care

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	3000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7948
Ander register	METC Maxima MC Veldhoven : METC L19.039 / N19.032

Resultaten