Intrapartum non-invasive electrophysiological monitoring: F2-study.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24697

Bron
Nationaal Trial Register

Verkorte titel
F2-study

Aandoening

non-invasive fetal ECG
fetal monitoring
labour

niet-invasief foetaal ECG
foetale monitoring
bevalling

Ondersteuning

Primaire sponsor: Maxima Medical Center, Veldhoven
The Netherlands
Overige ondersteuning: European grant Horizon 2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main goal of this validation study is to assess accuracy and reliability of monitoring of the fetal heart rate (FHR) by non-invasive fetal ECG (NI-fECG) using the Atlantis/Parides device. Since conduction of electrical signals may depend on the presence of amniotic fluid, we aim to study both FHR measurements in (part of) the period before membranes have (been) ruptured (in comparison to Doppler ultrasound (DU)), as well as after membranes have (been) ruptured (in comparison to the fetal scalp electrode (FSE, gold standard)).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Since there is much debate about the poor specificity of the cardiotocogram (CTG), additional techniques for fetal surveillance during labour have been developed. The disadvantage of these techniques, such as fetal blood sampling (FBS) and ST-analysis of the fetal electrocardiogram (ECG; STAN), is that they are invasive and can only be performed when membranes have ruptured. Non-invasive fetal ECG (NI-fECG) monitoring can overcome these disadvantages, by providing both an accurate fetal heart rate (FHR) and information on the fetal ECG morphology, both in a non-invasive way.

Objective: This study aims to validate NI-fECG monitoring as an accurate and reliable monitoring technique for fetal surveillance during labour. The aim of this validation is to work towards clinical implementation of NI-fECG monitoring.

Study design: This study is designed as a cross-sectional observational study, with a prospective nature.

Study population: Pregnant women who are in labour, carrying a healthy, singleton fetus in cephalic presentation, with a gestational age between 37 and 42 weeks. We aim to include 100 patients.

Intervention (if applicable): In addition to standard intrapartum monitoring by fetal scalp electrode (FSE) with tocodynamometer, eligible patients will also receive a transabdominal, non-invasive fECG patch, from the moment of start of fetal monitoring until the end of delivery. Also, at several moments during labour fetal position will be checked by short ultrasound measurements.

Main study parameters/endpoints: The main endpoint of this study is to assess the accuracy

and reliability of the NI-fECG monitorings for FHR and MHR. This will be compared to the accuracy of the gold standard FSE monitoring and pulse oximetry, respectively. Electrohysterogram (EHG) signals retrieved by the non-invasive fECG patch will be analysed and compared with the tocodynamometer/intrauterine pressure catheter (IUPC). Furthermore, fECG waveform details will be analysed and relevant information will be correlated to several clinical maternal and fetal parameters..

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation in this validation study will cause no risk for the patient. There is a very small chance that participating patients experience skin irritation or a minor allergic (local) reaction to the skin electrodes from the NI-fECG patch.

Doel van het onderzoek

Since there is much debate about the poor specificity of the cardiotocogram (CTG), additional techniques for fetal
surveillance during labour have been developed. The disadvantage of these techniques, such as fetal blood
sampling (FBS) and ST-analysis of the fetal electrocardiogram (ECG; STAN), is that they are invasive and can
only be performed when membranes have ruptured. Non-invasive fetal ECG (NI-fECG) monitoring can overcome
these disadvantages, by providing both an accurate fetal heart rate (FHR) and information on the fetal ECG
morphology, both in a non-invasive way.

Onderzoeksopzet

During labour.

Onderzoeksproduct en/of interventie

In addition to standard intrapartum monitoring by fetal scalp electrode (FSE) with tocodynamometer, eligible patients will also receive a transabdominal, non-invasive fECG patch, from the moment of start of fetal monitoring until the end of delivery. Also, at several moments during labour fetal position will be checked by short ultrasound measurements.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Pregnant women who are in labour, carrying a healthy, singleton fetus in cephalic presentation, with a gestational
age between 37 and 42 weeks

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- < 18 years of age

- Multiple pregnanc y

- Fetus in breech pos ition

- Women with signs of feta l distress (abnormal CTG requiring immediate intervention)

- Women with a positive hepatitis B/C or HIV serology

- Women with idiopathic thrombocytopenia or other inh eritable hematologic diseases

- Dermatologic disease of the abdomen precluding preparation of the abdomen with a brasive paper - Women in
labour taking a shower or bath and women connected to external or implanted electrical stimulators

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-02-2018
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46764
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6886
NTR-old	NTR7064
CCMO	NL63732.015.17
OMON	NL-OMON46764

Resultaten