Antenatal electrophysiological cardiotocography in preterm gestations. An observational study to test the performance of a new device for fetal monitoring.

Gepubliceerd: 16-10-2019 Laatst bijgewerkt: 18-08-2022

The performance of the NFMS in the premature period will be enhanced due to changes in the algorithm compared to traditional CTG.

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

Samenvatting

ID

NL-OMON24580

Bron
Nationaal Trial Register

Verkorte titel
NEMO2436

Aandoening

Fetal monitoring

Ondersteuning

Primaire sponsor: Zuyderland Medisch Centrum
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of Quality judgements and Interpretability of CTG tracings for each interval of 2 weeks from 24 to 36 weeks of gestation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Traditionally, the antenatal CTG is performed with two transducers placed on the mother’s abdomen: one to monitor the FHR by Doppler ultrasound (DU) and the other at the uterine fundus to measure (frequency of) contractions by tocodynamometry (TOCO). Recently, it has become possible to perform CTG non-invasively through electrophysiology, by the Nemo Fetal Monitoring System (NFMS). This system is CE marked in 2018 for gestations of 21 weeks till childbirth. Data obtained with predecessor hardware in 2007 show a fall of success rate to 60% for identifying fetal QRS complexes by electrophysiology for the period from 27 to 36 weeks. Hardware changes have been made in the new NFMS in 2018.

Objective: The aim of this observational study is to evaluate the quality and interpretability of the CTG tracings made by NFMS (2018) at gestational ages of 24 to 36 weeks.

Study design: Observational study.

Study population: In total 42 pregnant women who visit the outpatient clinic or are hospitalized in Zuyderland hospital will be asked for voluntary participation.

Intervention (if applicable): In total 72 CTGs will be made. In 36 patients, 1 CTG obtained by electrophysiology of 30 minutes is made. In 6 patients, 6 CTGs will be made at intervals of 2 weeks gestation.

Main study parameters/endpoints: Quality and Interpretability (judged by three independent obstetricians).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Thirthy-six patients will be measured 30 minutes, including preparation 40 minutes. Six patients will be measured 6 times, in total 6 x 40 minutes. Acquiring the CTG by NFMS carries virtually no risks. In less than 5% a temporarily redness of the skin of the abdomen appears, that will spontaneously disappear within 24 hours after the measurement.

Doel van het onderzoek

The performance of the NFMS in the premature period will be enhanced due to changes in the algorithm compared to traditional CTG.

Onderzoeksopzet

1 registration between 24 -36 weeks of gestation. In 6 patients 6 registrations in this time period with an interval of 2 weeks.

Contactpersonen

Publiek

Zuyderland Medisch Centrum
Jonas Ellerbrock

088-4597777

Wetenschappelijk

Zuyderland Medisch Centrum
Jonas Ellerbrock

088-4597777

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Singleton pregnancy
Gestational age between 24+0 and 35+6 weeks

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Maternal age under 18 years
Known fetal anomalies
Abdominal skin not intact or irritated
Implanted or external electrical stimulators (e.g. pacemaker)

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 nog niet gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	16-10-2019
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	NL8090
Ander register	METC Z : Z2019136

Resultaten