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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24580

Source
Nationaal Trial Register

Brief title
NEMO2436

Health condition

Fetal monitoring

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Ability to enhance performance of cardiotocography by electrophysiological registration.

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	42
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	16-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8090
Other	METC Z : Z2019136

Study results