Non-invasive electrophysiological monitoring on the obstetric high

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To investigate the effect of implementing continuous antepartum eCTG monitoring at the OHC, on perinatal and maternal outcomes and obstetric care

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON56122

Source
ToetsingOnline

Brief title
NIEM-O study

Condition

- Neonatal and perinatal conditions

Synonym
Perinatal mortality and morbidity - Health condition of the (unborn) child

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: ZonMW,Maxima Medisch Centrum

Intervention

Keyword: Continuous electrophysiological fetal monitoring

Outcome measures

Primary outcome

a composite of perinatal mortality or major neonatal morbidity until hospital discharge. Major neonatal morbidity is defined as either: Intraventricular hemorrhage (IVH) grade three or more, Periventricular leukomalacia (PVL) grade two or more, Moderate or severe bronchopulmonary dysplasia (BPD), Necrotizing enterocolitis (NEC) grade two or more, or Retinopathy of prematurity (ROP) necessitating laser therapy.

Secondary outcome

Maternal mortality, neonatal morbidity, satisfaction for both patient and caregiver, duration of pregnancy, switch of monitoring method, duration of admission to the OHC, timing (planned or emergency) and number of obstetric interventions (such as caesarean section), and admission and duration of admission to the NICU (neonatal intensive care unit).

Additional objectives: The collected NFMS and demographic data will be used to develop and verify a mathematical model for the prediction of time until (preterm) birth, which may be used in clinical practice to reduce unnecessary OHC admissions and facilitate a better timing of interventions. Furthermore, data collected in this study (NFMS, accelerometric, annotated ultrasound) will be used for the development and verification of a mathematical model for the automated detection of fetal movements in NFMS data. This latter model might provide new opportunities in non-invasive monitoring of fetal health.

Study description

Background summary

Pregnant women in need for maternal and/or fetal monitoring are hospitalized at the obstetric high care (OHC) of Máxima Medical Center (MMC). They are monitored for up to three times a day with conventional cardiotocography (CTG). In the meantime they reside at the OHC, but the status of the fetus and uterine activity (UA) is not monitored. Nemo Healthcare developed a wireless abdominal electrode patch for measuring fetal heart rate (FHR) and UA: The Nemo Fetal Monitoring System (NFMS). Previous research on non-invasive electrophysiological CTG (eCTG) has yielded promising results in monitoring FHR and UA both during pregnancy and labor. With the use of eCTG technology, safe continuous 24/7 monitoring is possible, which is not possible with conventional cardiotocography. We hypothesize that by introducing continuous antepartum eCTG monitoring perinatal and maternal outcomes will improve

Study objective

To investigate the effect of implementing continuous antepartum eCTG monitoring at the OHC, on perinatal and maternal outcomes and obstetric care

Study design

A single center prospective cohort intervention study with historical controls.

Intervention

Eligible women will be prospectively included in the cohort receiving standard treatment: CTG monitoring intermittent up to three times a day. From these eligible women, a random sample (464) of the prospective cohort (511) will be offered to receive a new monitoring method: 24/7 eCTG monitoring with NFMS. In order to strengthen the comparison between the two groups (eCTG and standard treatment), additional data from 1400 women who received standard treatment in 2014-2019 will be collected retrospectively.

Study burden and risks

Participation in this study is expected not to cause any risk for the women or fetus*, because if registration using the abdominal patch is insufficient, a switch to the (intermittent) conventional CTG will be made which is available at the OHC. From that moment on decisions will be based on the conventional CTG monitoring system, which is standard care. The advantage of the NFMS is that it is wireless (allowing women to move), non-invasive, safe, makes continuous monitoring possible, and has the potential to improve maternal and neonatal

outcomes. There is a chance that participating women experience skin irritation or minor allergic (local) reaction to the skin electrodes from the abdominal patch. If this happens, it is possible to switch to standard care. No treatment is necessary if skin irritation occurs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

>=18 years old, Singleton pregnancy >=23+0 weeks of gestation,Requiring hospitalization to the OHC for maternal or fetal surveillance, Parents wishing for fetal monitoring

Exclusion criteria

Multiple pregnancy, insufficient knowledge of Dutch or English language
, Contraindications to abdominal patch placement (dermatologic diseases of the abdomen precluding preparation of the abdomen with abrasive paper), women connected to an external or implanted electrical stimulator (e.g. a pacemaker - exclusion due to possible signal interference), Fetal and/or maternal cardiac disease (i.e. arrhythmia, congenital defect), Treatment plan (with intervention planned) already made before inclusion is completed, and women admitted with a clinical diagnosis of sepsis with hypotension (i.e. septic shock).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2023
Enrollment:	511
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL82869.015.22