Implementation of intrapartum non-invasive electrophysiological monitoring

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To investigate the effect of eCTG monitoring versus conventional CTG monitoring during labour on mode of delivery, maternal and perinatal outcomes, costs and patient and health professional perspectives.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON56299

Source
ToetsingOnline

Brief title
NIEM-II study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Maternal and perinatal outcomes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Electrohysterography, Electrophysiological monitoring, Intrapartum, Non-invasive

Outcome measures

Primary outcome

Number of operative interventions during labour; caesarean section or

instrumental vaginal deliveries.

Secondary outcome

Secondary objectives:

eCTG compared with conventional CTG monitoring:

- To assess the duration of the first stage of labour in minutes.

- To assess the duration of the second stage of labour in minutes.

- To assess the timing and reason of operative interventions during labour.

- To assess the need of analgesia for pain reduction.

- To assess perineal laceration and the use of episiotomy.

- To assess how often FBS is performed during labour and the result of the

FBS.

- To assess neonatal and maternal mortality and morbidity.

- To assess patient and health care professional satisfaction by

questionnaires.

- The total costs during labour until six weeks postpartum.

For eCTG monitoring:

- To assess the amount of signal loss.

- To assess the frequency (percentage) of switch from the abdominal electrode

patch to the conventional system (i.e. doppler ultrasound or fetal scalp electrode with tocodynamometry) during labour, along with the reason and timing of switches and the success rate before and after the switch.

- To assess the EHG pattern and the amount of blood loss within the first 1.5 hour postpartum.

- To assess EHG pattern in relation to medication use and placental expulsion (during 1.5 hour postpartum).

- To assess EHG pattern before and after labour analgesia and the possible association of EHG pattern with labour analgesia.

Study description

Background summary

Conventional cardiotocography (CTG) has been used extensively for more than 50 years to monitor the fetal condition during labour, but since the rate of operative deliveries keeps rising, its ability to improve neonatal outcomes is unsatisfactory. A transabdominal non-invasive and wireless alternative which overcomes the shortcomings of conventional methods is electrophysiological CTG (eCTG) monitoring. In eCTG the fetal heart rate (FHR) is measured by fetal electrocardiography (NI-fECG) and uterine activity (UA) by electrohysterography (EHG). Both NI-fECG and EHG have been proven more accurate and reliable than conventional non-invasive methods and are less affected by maternal body mass index (BMI). eCTG has the potential to reduce the number of interventions during labour and thereby to improve clinical outcomes for both mother and child.

Study objective

To investigate the effect of eCTG monitoring versus conventional CTG monitoring during labour on mode of delivery, maternal and perinatal outcomes, costs and patient and health professional perspectives.

Study design

A single centre cohort intervention study with historial controls.

Intervention

Eligible women will be prospectively included in the cohort receiving conventional CTG monitoring. From the eligible women in the prospective cohort a random sample (90.9%) will be offered eCTG monitoring via a computer generated random collection. Participants will receive eCTG monitoring from the start of fetal monitoring during labour until 1.5 hour after delivery. A retrospective cohort of 2100 women who received conventional CTG monitoring between 2019 and 2022 will be added to the prospective cohort for statistical analysis.

Study burden and risks

Participation in this study is expected not to cause any risk for the women or fetus. The NIEM pilot study has shown an overall success rate of eCTG monitoring with the Nemo Fetal Monitoring System (NFMS) of 94.5% during labour. In case eCTG registration is insufficient, a switch to the conventional CTG can be made.
The benefits of eCTG monitoring with NFMS include the fact that it is wireless (enabling women to move while giving birth), non-invasive, and has the potential to reduce the number of instrumental deliveries without compromising the maternal and neonatal outcomes. Women with the NFMS have a very small probability of developing skin irritation or a minor (local) allergic reaction to the skin electrodes from the abdominal patch. There is no need for treatment if skin irritation happens.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all
of the following criteria:
- Minimal age of 18 years old
- Pregnant women with a gestational age between 37+0 and 42+0 weeks and days
- Indication for fetal monitoring during labour
- Singleton fetus in cephalic position
- Oral and written informed consent is obtained

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded
from participation in this study:
- Insufficient knowledge of Dutch or English language
- Women with a multiple pregnancy
- Fetal and/or maternal cardiac arrhythmias
- 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, such as
Transcutaneous
Electro Neuro Stimulation (TENS) and pacemaker (because of disturbance
of the
electrophysiological signal)
- Treatment plan (with intervention plan) already made before inclusion is
completed
- Women who were included in the study, but when circumstances before
labour call for delivery
of the baby by unplanned caesarean section

- There is insufficient time for proper counselling
- 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):	20-11-2023
Enrollment:	5571
Type:	Actual

Ethics review

Approved WMO Date:	02-10-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-11-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-02-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	10-04-2024
Application type:	Amendment
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	NL82822.015.22