Implementation of intrapartum non-invasive electrophysiological monitoring: a pilot study.

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To determine the workability of the non-invasive abdominal electrode patch for implementation in clinical practice.

Ethical review	Approved WMO
Status	Completed
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55415

Source
ToetsingOnline

Brief title
Intrapartum electrophysiological monitoring: pilot study.

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
monitoring during labor

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Weijerhorst Stichting

Intervention

Keyword: Electrophysiological monitoring, Intrapartum, Non-invasive

Outcome measures

Primary outcome

Primary outcomes: Percentage of switch to FSE and tocodynamography during labor and the reason of switch.

Secondary outcome

Secondary outcomes:

Percentage and result of fetal blood sampling (FBS) in the primary and secondary stage of labor.

Association of EHG pattern and the amount of blood loss within the first one and a half hour postpartum.

Assocation of EHG pattern within the first one and a half hour postpartum and medication use and placental expulsion.

Association of EHG pattern and initiation of labor analgesia.

Other outcomes: This sample of patients will be a part of a greater study population to evaluate the effects of clinical implementation of NI-fECG and EHG monitoring on neonatal and maternal outcome. Retrospectively we will correlate fECG waveform details to clinical parameters and outcomes.

Study description

Background summary

Cardiotocography is used for continuous fetal monitoring during labor. Fetal heart rate (FHR) and uterine activity (UA) measured over time generates a

cardiotocogram (CTG). Clinical decisions and interventions, such as an operative delivery, are based on the interpretation of the CTG. Invasive measurements generate the most accurate FHR by using fetal scalp electrode (FSE) and UA by using intra-uterine pressure catheter (IUPC). However, invasive measurement has several contra-indications, can only be used when membranes have ruptured and has the risks of complications. An alternative method of FHR and UA measurement is electrophysiology. Nemo Healthcare® developed a wireless abdominal electrode patch for measurement of the FHR and UA by using non-invasive fetal electrocardiography (NI-fECG) and electrohysterography (EHG). The Nemo® Fetal Monitoring System (NFMS) is validated in the F2 study (NL63732.015.17) and has been CE-approved in October 2018. However, the workability of the NFMS during labor needs to be studied.

Study objective

To determine the workability of the non-invasive abdominal electrode patch for implementation in clinical practice.

Study design

A prospective observational pilot study

Study burden and risks

Participation in this pilot 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 conventional CTG (FSE and TOCO) will be made which is available in each labor ward. 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 during delivery), non-invasive and has the potential to improve maternal and neonatal outcomes. Information on EHG pattern (UA) and the amount of blood loss within the first hour postpartum may be used in the future for management to prevent postpartum hemorrhage.
There is a very small chance that participating patients experience skin irritation or minor allergic (local) reaction to the skin electrodes from the abdominal patch.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Pregnant women with a gestational age between 36 and 42 weeks.
- Admission to the labor ward because of labor and indication for fetal monitoring during labor.
- Singleton fetus in cephalic presentation.
- 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:
- Women under the age of 18 years.
- Language barrier (other language than Dutch or English)
- Women with a multiple pregnancy.
- Fetal cardiac arrhythmias (detected and confirmed during pregnancy by ultrasound).
- Contraindications to abdominal patch placement (dermatologic diseases of the

abdomen precluding preparation of the abdomen with abrasive paper).
- Women in labor taking a bath (because the Bluetooth signal is disturbed and monitoring is impossible). It is possible to take a shower.
- Women connected to external or implanted electrical stimulators, such as Transcutaneous Electro Neuro Stimulation (TENS) and pacemaker (because of disturbance of the electrophysiological signal we want to measure, not because of danger for mother or child).
- Contraindications for monitoring using a FSE (coagulation disorders and maternal infections like HIV or hepatitis)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-01-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Nemo Fetal Monitoring System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-12-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	30-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-02-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-03-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-04-2021
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	NL68439.015.19

Register	ID
Other	NL8024

Study results

Date completed: 19-07-2021

Results posted: 22-06-2022

First publication
01-01-1900