Intrapartum non-invasive electrophysiological monitoring: F2 study

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This study aims to validate NI-fECG monitoring as an accurate and reliable monitoring technique for FHR, MHR and UA surveillance during labour. The aim of this validation is to work towards clinical implementation of NI-fECG monitoring.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Foetal complications
Study type	Observational non invasive

Summary

ID

NL-OMON46764

Source
ToetsingOnline

Brief title
F2

Condition

- Foetal complications

Synonym
non-invasive fetal electrocardiogram

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: EU Horizon 2020 subsidie (https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020)

Intervention

Keyword: fetal monitoring, labour, non-invasive fetal ECG

Outcome measures

Primary outcome

The main endpoint of this study is to assess the accuracy of the NI-fECG monitorings. This will be compared to the accuracy of the gold standard FSE monitoring.

Secondary outcome

To validate the monitoring of maternal heart rate measured by the Atlantis/Parides system as compared to standard methods of monitoring maternal heart rate during labour (for instance pulse oximetry or the pulse Doppler signal provided by the TOCO button).

To compare the EHG (electrohysterogram) signals retrieved by the Parides patch with the tocodynamometer (TOCO) or intra-uterine pressure catheter (IUPC).

Study description

Background summary

Since there is much debate about the poor specificity of the cardiotocogram (CTG), additional techniques for fetal surveillance and contrationmonitoring during labour have been developed. The disadvantage of these techniques, such as fetal blood sampling (FBS) and ST-analysis of the fetal electrocardiogram (ECG; STAN) and the intra-uterine pressure catheter, is that they are invasive and can only be performed when membranes have ruptured. Non-invasive fetal ECG (NI-fECG) monitoring can overcome these disadvantages, by providing an accurate fetal heart rate (FHR), maternal heart rate (MHR), uterine activity (UA) and information on the fetal ECG morphology, all in a non-invasive way.

Study objective

This study aims to validate NI-fECG monitoring as an accurate and reliable monitoring technique for FHR, MHR and UA surveillance during labour. The aim of this validation is to work towards clinical implementation of NI-fECG monitoring.

Study design

a cross-sectional observational study, with a prospective nature, that will take place in the MMC Veldhoven.

Study burden and risks

Participation in this pilot study will cause no risk for the patient. There is a very small chance that participating patients experience skin irritation or a minor allergic (local) reaction to the skin electrodes from the NI-fECG 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

Pregnant women who are in labour, carrying a healthy, singleton fetus in cephalic presentation, with a gestational age between 36 and 42 weeks

Exclusion criteria

- < 18 years of age
- Multiple pregnancy
- Fetus in breech position
- Women with signs of fetal distress (abnormal CTG requiring immediate intervention)
- Women with a positive hepatitis B/C or HIV serology
- Women with idiopathic thrombocytopenia or other inheritable hematologic diseases
- Dermatologic disease of the abdomen precluding preparation of the abdomen with abrasive paper - Women in labour taking a shower or bath and women connected to external or implanted electrical stimulators

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2018
Enrollment:	120

Type:	Actual

Medical products/devices used

Generic name:	Atlantis/Parides system
Registration:	No

Ethics review

Approved WMO Date:	22-12-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	19-03-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	11-06-2018
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

ID: 24697
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL63732.015.17
OMON	NL-OMON24697