Pilot study. Intrapartum non-invasive monitoring of the fetal electrocardiogram: PF2 study.

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This pilot study aims to explore the possible technical and practical problems that may be encountered when intrapartum NI-fECG monitoring is performed (PF2 study). The results of this pilot study will be the basis for a larger validation study...

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

Summary

ID

NL-OMON45988

Source
ToetsingOnline

Brief title
Non-invasive monitoring of the fetal ECG: PF2 study.

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: ECG, fetal electrocardiogram, fetal monitoring, non-invasive

Outcome measures

Primary outcome

The main endpoint is qualitative and descriptive of nature, based on a collection of practical and/or technical problems within the 50 NI-fECG monitorings.

Secondary outcome

Secondary study parameters are signal quality and signal loss. The two methods (FSE and NI-fECG) will be compared regarding signal quality and signal loss (FSE serves as gold standard). Also, fECG waveform details will be analysed and relevant information will be correlated to several clinical maternal and fetal parameters. furthermore, the EHG signals retrieved with the NI-fECG wil be analysed.

Study description

Background summary

Since there is much debate about the poor specificity of the cardiotocogram (CTG), additional techniques for fetal surveillance 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), 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 both an accurate fetal heart rate (FHR) and information on the fetal ECG morphology, both in a non-invasive way.

Study objective

This pilot study aims to explore the possible technical and practical problems

that may be encountered when intrapartum NI-fECG monitoring is performed (PF2 study). The results of this pilot study will be the basis for a larger validation study towards clinical implementation of NI-fECG monitoring (VF2 study).

Study design

This pilot study is designed as 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

< 18years 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):	21-09-2016
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Atlantis/Parides
Registration:	No

Ethics review

Approved WMO Date:	30-06-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-04-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	29-08-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-10-2017
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	NL57833.015.16