Antenatal electrophysiological cardiotocography in preterm gestations. An observational study to test the performance of a new device for fetal monitoring.

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

Summary

ID

NL-OMON49797

Source
ToetsingOnline

Brief title
NEMO2436

Condition

- Foetal complications

Synonym
Fetal Monitoring

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: de leverancier stelt de apparatuur (tijdelijk) beschikbaar

Intervention

Keyword: Electrophysiology, Fetal, Monitoring, Premature

Outcome measures

Primary outcome

Percentage of Quality judgements and Interpretability of CTG tracings for each

interval of 2 weeks from 24 to 36 weeks of gestation.

Secondary outcome

N.A.

Study description

Background summary

The condition of the unborn baby is usually assessed using cardiotocography. The heart rate of the baby and the activity of the uterus are recorded simultaneously. Sometimes that technique is difficult or the patients find the tires they get to their belly annoying. By a new technique it is now possible to do this research with a plaster on the mother's belly. This patch captures the electrical signals from both the heart of the mother, the heart of the baby and the uterine muscle and transmits it wirelessly through a wireless transmitting signal. This system is called the Nemo Fetal Monitoring System (NFMS).
We know that the NFMS works well above 37 weeks of gestational age. Now we want to test whether this is also successful in unborn babies between 24 and 37 weeks.

Study objective

Nemo Healthcare B.V. recently developed a new technique for monitoring the unborn baby. This technique is already widely used in unborn babies over 37 weeks of gestational age. The purpose of this study is to examine if that new

technique is also successful in unborn babies between 24 and 37 weeks gestational age. Therefore, we will perform a 30-minute measurement at 36 pregnant volunteers who are visiting (one of) the gynecologists of the Zuyderland Medisch Centrum. In addition, in 6 pregnant volunteers, we will perform 6 times the same measurement during pregnancy. This serial measurements are planned to get more information about the vernix caseosa; is this an interference which is transiently seen in certain patient and deminishes during progression of pregnancy or is this seen in certain patients and does not dissapear when time is evolving.

Study design

Observational study

Study burden and risks

Participants wil have tot invest 40minutes of their time. 5 minutes for the preparation and 30minutes registration. There are very little risks on participation in this study, except for <5% local irritation on the abdominal skin which will disappear within 24 hours spontaneously.

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

Singleton pregnancy
Gestational age between 24+0 and 35+6 weeks

Exclusion criteria

Maternal age under 18 years
Known fetal anomalies
Abdominal skin not intact or irritated
Implanted or external electrical stimulators (e.g. pacemaker)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2021
Enrollment:	42
Type:	Actual

Medical products/devices used

Generic name:	Nemo Fetal Monitoring System

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-01-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL71839.096.19