Monitoring and diagnosing fetal cardiac (ar)rhythmias per CTG-registration and fetal ECG by the Monica AN24tm.

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The main goal of this study is to examine the clinical applicability of the Monica AN24*, for the use of this device in the LUMC for prolonged CTG-registrations in high risk pregnancies and particularly in monitoring fetal cardiac arrhythmias. The...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON34791

Source
ToetsingOnline

Brief title
Fetal monitoring by the Monica AN24*.

Condition

- Cardiac and vascular disorders congenital
- Foetal complications

Synonym
congenital heart arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac (ar)rhythmias, Fetal cardiac physiology, Fetal electrocardiogram, Non-invasive

Outcome measures

Primary outcome

Totally, there will be made three times a CTG-registration by the Monica An24* and two times a conventional CTG registration per participant. Percentages of successful registration will be noted and are classified in groups (very good, good, temperate and bad). This will be done in the CTG-registrations of the Monica AN24* and in the current CTG-registrations and expressed per time interval; they will be compared with the chi-square test.

The CTG-derivations (in percentages) from the Monica AN24* of the participants, divided by Body Mass Index (BMI<19, BMI 19-24,9, BMI 25-29,9, BMI >= 30) are compared with the chi-square test.

Using special software the fetal ECGs will be derived from CTG-registrations from the Monica AN24*. Per time-interval the obtained fECGs will be judged and divided by differences in quality and usefulness. The fECGs are judged on P-wave, PR-interval, QRS-complex, T-wave and QT-interval. The fECG will be divided into quality categories, dependent on identifiable elements of the ECG: good (3 elements recognizable), moderate (QRS-complex and P-wave or T-wave recognizable), poor (only QRS-complex recognizable).The fECG will be examined by two independent and blinded pediatric cardiologists, without knowledge of the ultrasound results. The pediatric cardiologists will judge the fECGs on quality and measure PR-, ST- and QT-interval and QRS-complex. The quality data

of the fECG*s per time interval will be compared by chi-square test.

Atrioventricular conduction times obtained by ultrasound tests will be compared

with fECGs in time interval week 20-24 and it will be exposed in a

Bland-Altmanfigure.

Secondary outcome

nvt

Study description

Background summary

Fetal arrhythmias occur in as many as 1 to 3% of all pregnancies. Fetal cardiac arrhythmias are mostly benign, but they can result in fetal hydrops which can lead to intra-uterine mortality and premature birth. At the gestational age of 16 weeks, it*s possible to judge fetal heart frequency. The fetal cardiac conduction system is developed and there is a regular heart rhythm between 100 and 180 bpm.
Electrocardiogram (ECG) is the basis to diagnose cardiac arrhythmias. Today fetal cardiac arrhythmias can be diagnosed just indirectly by measurements of echocardiography and fetal monitoring is achieved by ultrasound CTG-registrations at hospital. These tests are snapshots and specialistic expertise is necessary. Information of cardiac electric conduction of the fetal heart cannot be acquired. Monitoring of fetal cardiac arrhythmias is only possible by regularly making CTG-registrations and echocardiography in which heart rhythm, cardiac function and fetal condition are assessed. Fetal ECGs may be an extra tool in diagnosis and detection of fetal cardiac arrhythmias.
Fetal electrocardiogram (fECG) is a technique, which isn*t clinically applied yet, because of some technical problems as low voltage signal and many noise, like maternal heart beating.
Recent research on fECG showed that non-invasive fECGs are possible and more detailed information will be given about fetal heart activity and conduction comparing with measurements by echocardiography. However difficulties in detecting small fetal QRS-complexes are shown in this research.
An other study shows fECG through maternal abdomen, suppressing maternal ECG. Other noise like electronic signals, intra-abdominal signals, myo-electric signals of abdominal muscles and uterine activity (especially during labor) are filtered by algorithms and match filtering by Independent Component Analysis (ICA). Quality of fECGs may be dependent on presence of vernix caseosa (from gestational age of 28 weeks) and quantity of amnion fluid, by influencing the

conduction of the electrical signals. Now, clinical fetal monitoring occurs by echographic CTG-registration. Ultrasound waves are sent into the maternal abdomen and the CTG device measures fetal heart frequencies by catching the reflection. Fetal condition can be judged after 30 minutes registration based on fetal heart rhythm (variability, accelerations and decelerations). This technique has some disadvantages. The pregnant women are fixed at bed during registration, ultrasound has to be sent to the abdomen continuously, quality of prolonged CTG-derivations depends on fetal movements, electrodes has often to be replaced by trained staff. Pregnant women with adipositas have an additional disadvantage in quality of registration, because ultrasound waves penetrate badly through fatty tissue. At this moment, prolonged CTG registration is impractical and loaded for the pregnant women.
The Monica AN24* is a new CTG method. It passively registries electric signals from the maternal abdomen by standard stick-electrodes measuring fetal heart beats. It is now possible to derive a fetal ECG from the raw data of the CTG-registrations by the Monica. This makes it possible to measure elements of fetal heart conduction, like PR-interval, width of QRS-complexes and QT-intervals. Also true variability of heart frequency could be pointed out, the *real* R-R variability.
The Monica AN24* has a lot of benefits: it is a passive method, and electric signals better penetrate fatty tissue compared with ultrasound, so adipositas theoretically has little influence on the quality of the fECGs. It is a small, bearable monitor; the women will be mobile during registration. So, prolonged continuous registration for fetal monitoring in fetal cardiac arrhythmias will be less loaded for the pregnant women.
The Monica AN24* isn*t dependent on fetal movements, because of the electric activity registered by the electrodes and replacement of the electrodes isn*t necessary. All data are saved at the little monitor, so registration at home will be possible. Monica AN24* registrations are mentioned since a gestational age of 20 weeks.
The section Obstetrics of the LUMC has a Monica AN24* available with the aim to use the new equipment for fetal monitoring, by prolonged and (eventually home) CTG-registrations by pregnant women with fetal cardiac arrhythmias. There are a few studies which have examined that gestational age (vernix caseosa, amount of amnion fluid) and effects of BMI could influence the quality of electrical CTG-registrations. The possibility of constructing complete fECGs, with identification of P-waves, QRS-complexes and T-waves isn*t sufficient examined yet.

Study objective

The main goal of this study is to examine the clinical applicability of the Monica AN24*, for the use of this device in the LUMC for prolonged CTG-registrations in high risk pregnancies and particularly in monitoring fetal cardiac arrhythmias. The CTG registrations by the Monica AN24* will be validated and the influence of gestational age and BMI on quality of the registrations will be examined.

Also, the possibilities to derive fetal ECGs from CTG-registrations of the Monica AN24* will be examined.

• Is the quality of the CTG registrations by Monica AN24* through maternal abdomen comparable with conventional ultrasound CTG-registrations?
• Does gestational age and maternal BMI influence the CTG quality of the Monica AN24*?
• Is the Monica AN24* able to produce reliable fetal ECG-registration derived from the CTGs by the Monica AN24*?
• Is the Monica AN24* CTG-registration useful for registering at home?
• What could be the role of the Monica AN24* by the diagnosis and treatment of fetal cardiac arrhythmias?

Study design

Observation study, patient series. First, the new technique will be valuated. A database will be created including as many as possible pregnant women with a singleton pregnancy. Participants will be approached as soon as possible, but regardless before gestational age of 20 weeks. All subjects get a questionnaire about gestational age, BMI, parity and (congenital) abnormalities by other pregnancies. Subsequently the participants will be divided in categories based on their BMI (BMI<19, BMI 19-24,9, BMI 25-29,9, BMI >= 30). Also gestational age will be classified in time intervals. Per interval the participant gets at minimum one CTG-registration. The test will be at the same day when the participant has an appointment with gynecologist or obstetrician at the section Obstetrics of the LUMC. Two times both a CTG-registration by the Monica AN24* as a conventional CTG registration will be made. Both registrations will take 30 minutes, so together it will no longer take than one hour extra per appointment.
By Participants a standard ultrasound (SEO) is made at gestational age of 20 weeks. Thickness of maternal abdomen, fetal heart function, heart rhythm and conduction of fetal heart will be regarded extra by 2D, M-mode and Doppler echocardiography. This will take about 10 minutes more time compared to the standard ultrasound.
At the end of the study CTG-registrations will be judged by the principal investigator. Percentages of registered time will be noted, there will be no paper strip, but the registration will be saved anonymous and digital. These measures are taken, because clinical relevance of CTG-registrations by an uncomplicated pregnancy is unknown.

Time interval Different tests
in weeks of gestational age Monica AN24 CTG registration Current CTG registration SEO with prenatal echocardiography

19-24 weeks
x
x

25-29 weeks
x x
30-34 weeks
x x

Study burden and risks

This study uses non-invasive techniques. CTG-registration by the Monica AN24* is a safe method, without risks for mother and/or unborn child. Electronic activity will be passively received by standard stick-electrodes on the maternal abdomen. The study will take about three times one hour extra for the participant. Appointments will be coupled to already existing appointments with obstetrics or gynecologist; so there is no need for extra traveling. An allergic reaction at brown tape is possible; we will attend the participants before placing the electrodes.
It is non-invasive research, minimal loaded, without risks for mother or unborn child.

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

Healthy pregnant women, above the age of 18, singleton pregnancy, voluntarily, minimal gestational age of 19 weeks, under care of the department of obstetrics of the LUMC.

Exclusion criteria

Multiple pregnancies, underage, incapable of giving informed consent, no informed consent given

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	12-04-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL31816.058.10