Pilot study: Evaluation of the non-invasive fetal electrocardiogram, regarding the diagnosis of congenital heart diseases.

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Cross-sectional study: To detect the normal range of amplitudes and segment intervals of the fECG. Case-cohort study: To compare the fECG between healthy fetuses and fetuses with various forms of severe CHD. To determine the diagnostic value of fECG…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44934

Source
ToetsingOnline

Brief title
Pilot study: Diagnosing congenital heart diseases with fetal ECG.

Condition

- Congenital cardiac disorders
- Neonatal and perinatal conditions

Synonym
Congenital heart diseases

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Er is geen financiering voor dit onderzoek.

Intervention

Keyword: Congenital heart diseases, Fetal electrocardiogram

Outcome measures

Primary outcome

The recordings are performed between 08.00 h and 16.00 h during appointments at the outpatient clinic and will take no longer than 45 minutes. The fECG is a non-invasive, transabdominal approach with self-adhesive electrodes placed in a fixed configuration. A non-invasvie, electrophysiologic monitor is used to record and store the electrical activity on the maternal abdomen. During the fECG measurement an ultrasound is made four times for a short period, to determine the position of the fetus in utero. The collected data will be analysed off-line. The maternal ECG is removed, without effecting the present fECG-complexes. The amplitudes (P-, QRS- and T-top), segment intervals and heart axis will be calculated.

Secondary outcome

To compare the fECG between healthy fetuses and fetuses with various forms of severe CHD. To determine the diagnostic value of fECG to detect CHD.

Study description

Background summary

Congenital heart disease (CHD) is a severe condition, which needs early

detection and treatment. The current method for detecting CHD during pregnancy is a structural ultrasound at week 20 of gestational age. Only 25 to 60 per cent of the cases are detected by this method. Therefore, there is need for a technique with a higher specificity, in order to guarantee early detection. This new technique could be the transabdominal non-invasive fetal electrocardiogram (fECG). In order to detect the different abnormalities, the normal ranges of amplitudes, segment intervals and the heart axis (with 95% confidence intervals (CI)) of the fECG have to be established.

Study objective

Cross-sectional study: To detect the normal range of amplitudes and segment intervals of the fECG.
Case-cohort study: To compare the fECG between healthy fetuses and fetuses with various forms of severe CHD. To determine the diagnostic value of fECG to detect CHD.

Study design

This study will be performed as a cross-sectional and a case-cohort study. The first part of the research (cross-sectional study) will be performed in the Máxima Medical Center in Veldhoven (MMC) and Diagnostic Centre Eindhoven (DVU). This study focuses on the normal range of amplitudes, segment intervals and heart axis (all with 95% CI) of the fECG. The second part (case-cohort study) will focus on the values of the amplitudes, segment intervals, heart axis (with 95% CI) and ventricle volumetry measurements of fetuses with diagnosed form of severe CHD like Fallot*s tetralogy. CHD is detected by the current screening method, the structural ultrasound. The center at which the CHD is diagnosed, informs the patient about our study and contacts us if the patient is willing to participate in the study. The participating centers are asked to make a 3D echocardiography of the foetus. Centers involved in this research are the tertiary care hospitals: MMC Veldhoven, Radboud Medical Center Nijmegen (UMCN), Academic Medical Center (AMC) Amsterdam en Leiden University Medical Center (LUMC).

Study burden and risks

There are no physical risks or side effects of the fECG measurement or the ultrasound to the mother, fetus or third parties. Allergy or irritation from the used electrodes or the conduction gel are the only conceivable problems. This is rare. All of the used equipment is approved by the Medical Technical Service Department of the Máxima Medical Centrum in safety tests.The conduction gel is widely used for ultrasonography and is safe to use. In pregnant women, one must always bear in mind the risk of aortocaval compression. From midpregnancy onwards, the enlarged uterus compresses both the inferior vena cava and the lower aorta when the patient is lying in supine position. To

prevent this from happening, the patient will be placed in a semi-recumbent position or left lateral tilt position during the measurements.

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

Cross-sectional study: pregnant women, carrying a healthy, singleton fetus with a gestational age between 18 and 24 weeks. Participants must be aged older than 18 years. Case-cohort study: pregnant women, carrying a singleton fetus with a known severe congenital heart disease or cardiac arrhythmia, with a gestational age between 18 and 30 weeks. Participants must be aged older than 18 years. Severe CHD will be defined as a form of CHD with hemodynamic importance and/or an operation or intervention in the first year of life.

Exclusion criteria

Women under the age of 18 years old, multiple pregnancies, women carrying a fetus with a known congenital abnormality other than congential heart disease.

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):	26-05-2014
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO Date:	22-05-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-03-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	28-04-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-10-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-01-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-01-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-08-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-08-2017
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

ID: 20695
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL48535.015.14
OMON	NL-OMON20695