Pilot study: Diagnosis of congenital heart disease with fetal ECG

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20695

Source
NTR

Brief title
ConFEs

Health condition

Congenital heart defects

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: Máxima Medisch Centrum
Nemo Healthcare

Intervention

Outcome measures

Primary outcome

Primary Objective: To establish the normal ranges or values of amplitudes, segment intervals (with 95% confidence intervals) and the heart axis of the fECG in a healthy fetus.

Secondary outcome

Secondary Objective: 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

Rationale: 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 around 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 sensitivity, 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 and segment intervals of the fECG have to be established.

Objective: To detect the normal range of amplitudes, segment intervals and the heart axis of the fECG. To compare fECG of healthy fetuses and fetuses with severe 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 Máxima Medical Center Veldhoven (MMC) and Diagnostic Center Eindhoven (DVU). This study focuses on the normal range of (relative) amplitudes and segment intervals of the fECG. The second part (case-cohort study) will focus on the values of the amplitudes and segment intervals of fetuses diagnosed with a severe CHD like Fallot’s tetralogy. CHD is diagnosed by the current method for prenatal screening, 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. Centers involved in this research are the tertiary care hospitals: Máxima Medical Center Veldhoven (MMC), Radboud Medical Center Nijmegen (UMCN), Acadamic Medical Center Amsterdam (AMC) and Maastricht University Medical Center (MUMC).

Study population: In the cross-sectional study, 300 pregnant patients, aged older than 18 years, with a gestational age of 18 – 24 weeks will be included to obtain 200 measurements with good fECG signal quality. The fetuses have to be healthy, without any known congenital heart abnormalities. For the case-cohort study, the fetus must be diagnosed with a severe, hemodynamic important CHD. We will include 10 patients per severe CHD with a good signal quality. The types of CHD we will include are: Fallot’s Tetralogy, hypoplastic left heart syndrome, aortic stenosis, pulmonary atresia, transposition of the great vessels, coartcation of the aorta and an atrial ventricular septal defect.

Intervention: The fECG is a non-invasive, transabdominal approach with self-adhesive electrodes. During the fECG measurement an ultrasound is made four times for a few minutes to determine the position of the fetus. 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 patient will be lying on a comfortable bed in a semi-recumbent position.

Main study parameters/endpoints: To determine the normal values and ranges of amplitudes, segment intervals and heart axis of healthy fetuses with a gestational age of 18 to 24 weeks. To determine the differences in fECG between healthy fetuses and fetuses diagnosed with severe CHD.

Study objective

We hypothesize that the non-invasive fECG combined with the SEO has a higher detection rate for diagnosing CHD compared to the SEO alone. We expect that the fECG can detect additional details about the development and etiology of CHD.

Intervention

Transabdomonal non-invasive fetal electrocardiogram

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in the cross-sectional study, a subject must meet all of the following criteria:

- Pregnant women carrying a healthy fetus

- Aged older than 18 years

- Gestational age between 18 and 24 weeks

In the case-cohort study, a subject must meet all of the following criteria:

- Pregnant woman carrying a fetus with a known severe CHD (Fallot's Tetralogy, hypoplastic left heart syndrome, aortic stenosis, pulmonary atresia, transposition of the great vessels, coartcation of the aorta and an atrial ventricular septal defect)

- Aged older than 18 years

- Gestational age between 18 and 24 weeks

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Multiple Pregnancies

- Insufficient understanding of Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-05-2014
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44934
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5669
NTR-old	NTR5906
CCMO	NL48535.015.14
OMON	NL-OMON44934

Study results

Summary results

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