Fetal myocardial deformation assessed by speckle tracking; a longitudinal cohort study in the (ab)normal pregnancy;Substudy: fetal heart rate variability and ECG waveform parameters in the IUGR pregnancy

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To investigate the effect of increasing gestation on fetal myocardial deformation values.To explore fetal heart rate variability and fetal ECG waveform parameters in both healthy and growth-restricted fetuses, measured with non-invasive fetal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON48690

Source
ToetsingOnline

Brief title
Development of the fetal heart

Condition

- Cardiac disorders, signs and symptoms NEC
- Foetal complications

Synonym
normal fetal cardiac development and fetal heart rate variability in pregnancy and fetal heart development and heart rate variability in complicated pregnancies

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: schenking van Stichting de Weijerhorst

Intervention

Keyword: fetal ECG, fetal myocardial deformation, remodeling, Speckle tracking

Outcome measures

Primary outcome

Normal myocardial deformation values throughout gestation will be investigated.

Secondary outcome

Comparison of normal values of myocadial deformation throughout the pregnancy

with values of myocardial deformation as measured in complicated pregnancies.

Fetal heart rate variability and fetal ECG waveform parameters in healthy and

growth-restriced fetuses.

Study description

Background summary

Speckle tracking echocardiography (STE) offers the potential to measure myocardial deformation. Myocardial deformation imaging has been demonstrated a high sensitivity for detecting preclinical myocardial dysfunction in various pathological conditions characterized in adults. STE in fetal cardiology is still challenging but might be a good tool to predict fetal cardiac function and fetal well-being, especially in pregnancies complicated by placental dysfunction. Normative data for fetal myocardial deformation haven not been comprehensively described in a longitudinal cohort. The effect of increasing gestation on these values need further investigation in healthy, and in complicated pregnancies before STE can be introduced in daily clinical

practice.

Fetal cardiac remodeling due to hypoxia also leads to decreased fetal heart rate variability, which is an important parameter for fetal wellbeing. Quantitative assessment of fetal heart rate variability is not possible with the current method for fetal monitoring, cardiotocography, because it does not provide beat-to-beat information on the fetal heart rate. The non-invasive fetal electrocardiography technique however, can provide beat-to-beat information on the fetal heart rate.

Study objective

To investigate the effect of increasing gestation on fetal myocardial deformation values.

To explore fetal heart rate variability and fetal ECG waveform parameters in both healthy and growth-restricted fetuses, measured with non-invasive fetal electrocardiography.

Study design

Longitudinal prospective cohort study for uncomplicated pregnancies.
Explorative pilot case control study for pregnancies complicated with fetal growth restriction, gestational diabetes and hypertensive disease.

Study burden and risks

No extend of burden nor risks for the participant to be expected.
There is no befenefit for the participant.
Ultrasound examinations will be performed on a 4 weekly base from 20 to 40 weeks gestational age (or until delivery if delivery occurs before 40 weeks GA). Growth restricted fetuses will have a weekly ultrasound, included in their regular follow up appointments.

fECG will be perfomred once in the healthy pregnant subject, it will be perfomred on a weekly base in the growth restricted cohort.

Contacts

Public
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Scientific
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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, uncomplicated pregnancy, singleton without suspicion of congenital anomalies.
Pregnant women, pregnancy complicated by fetal growth restriction, singleton without suspicion of congenital anomalies

Exclusion criteria

<18 years
multiple pregnancy
pre existent hypertensive disease or diabetes

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-03-2019
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: 20837
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64999.015.18
Other	NTR: TC 7132
OMON	NL-OMON20837