

Fetal heart rate variability in growth-restricted fetuses. Substudy of NTR 7132 'Fetal myocardial deformation throughout pregnancy'.

No registrations found.

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

Summary

ID

NL-OMON27824

Source

Nationaal Trial Register

Health condition

Pregnancy, Fetal heart rate variability, Fetal growth restriction

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

- To determine if there a significant differences in fetal heart rate variability between fetuses with FGR and healthy fetuses measured with the non-invasive fetal electrocardiogram and matched for gestational age.

- To explore the process of fHRV parameters changing during gestation in fetuses with fetal growth restricted/tardation.
- To determine if there is a relation between STE values and fHRV parameters in growth-retarded fetuses.

Secondary outcome

- We want to explore the feasibility to extract electrocardiographic waveforms from measurements done with the NI-fECG technique. These include beat-to-beat variations (RR-interval), PR interval, QRS interval, QT interval and ST segment. We will correlate this information to clinical parameters, such as neonatal outcome (pH, Apgar score) and several maternal parameters (BMI, analgesia during labour, gestational age, use of medication, maternal health status). Moreover, if possible in this dataset, we aim to provide reference values of the durations of the various waveform details.

Study description

Background summary

Women, pregnant from a growth restricted fetus, will be asked for a fetal electrocardiography measurement on a weekly base from the moment of diagnosis until birth. Pregnant women, pregnant from a singleton, will be asked for one-time fetal electrocardiography. Inclusions from the control group will be matched for gestational age with the FGR group.

FECG measurements will take 40 minutes. Women are lying in a semi recumbent position. The abdominal skin is prepared with abrasive paper before application of the electrode patch. During the measurement, a short fetal positioning ultrasound is performed every 15 minutes. Data is analyzed offline. We want to study the differences in fetal heart rate variability between healthy and growth restricted fetuses.

Study objective

FGR induced cardiac remodeling also affects fetal heart rate variability (fHRV). Chronic hypoxia in growth-restricted fetuses due to placental dysfunction can interfere with maturation of the autonomic nerve system, leading to a decrease in fHRV. This can be measured with fetal electrocardiography.

Study design

Pregnant women, pregnant from a singleton, will be asked for a one-time only fetal electrocardiographic measurement. Inclusions for the control group are matched for gestational age with FGR inclusions. Women, pregnant from a growth restricted fetus, will be measured on a weekly base from the moment of diagnosis until birth.

Intervention

The non-invasive fetal electrocardiogram is a non-invasive, transabdominal recording method. It uses multiple electrodes on the maternal abdomen to determine the fetal and maternal heart rhythm and some parts of the heart's electrical conduction system and it registers the contractions. Women will be lying down in a semi recumbent position during the measurement. The electrode patch will be applied by trained staff, to make sure application and connection will be done in the correct way and avoid unnecessary technical problems. Before applying the electrode patch on the abdomen, the abdominal skin will be cleaned with water and soap. Next, the abdominal skin will be prepared with abrading paper to remove dead skin cells, as this is essential for proper guidance of the electrical currents and to optimize the impedance. This is a one-time action as the adhesive properties of the patch ensure that it will remain on the same location throughout the delivery. The measurement will last 40 minutes. During the measurement, short ultrasound measurements will be made (at the start of the measurements and approximately every 15 minutes) to determine the position of the fetus. Information concerning the fetal position is necessary for the analysis of the fECG waveforms. Data will be stored and analyzed offline.

Contacts

Public

Lore Noben
Maxima Medical Center Veldhoven
Veldhoven
The Netherlands

Scientific

Lore Noben
Maxima Medical Center Veldhoven
Veldhoven
The Netherlands

Eligibility criteria

Inclusion criteria

- Singleton pregnancy
- Age >18 years
- Control group: healthy fetuses

- FGR group: Pregnancies complicated with Fetal growth restriction (FGR) defined as:

Fetal Growth Restriction: estimated fetal weight

-Gestational age >19 weeks

Exclusion criteria

-Multiple pregnancies

-Age <18 years

-Suspicion of congenital anomalies that could possibly interfere with fetal cardiac function.

-Fetal cardiac arrhythmia

-Pre-existent maternal disease that might influence on fetal development; including diabetes mellitus, pre-existent hypertensive disease, auto-immune disease

-Insufficient understanding of Dutch language

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	02-07-2018
Enrollment:	0

Type: Anticipated

Ethics review

Positive opinion

Date: 02-07-2018

Application type: First submission

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
NTR-new	NL7141
NTR-old	NTR7339
Other	NL64999.015.18 METC Maxima Medical Center : W18.038

Study results