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

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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....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27824

Bron
Nationaal Trial Register

Aandoening

Pregnancy, Fetal heart rate variability, Fetal growth restriction

Ondersteuning

Primaire sponsor: Maxima Medisch Centrum
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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 restrictedtardation.
- To determine if there is a relation between STE values and fHRV parameters in growth-retarded fetuses.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 wit fetal electrocardiography.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-07-2018
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7141
NTR-old	NTR7339
Ander register	NL64999.015.18 METC Maxima Medical Center : W18.038

Resultaten