Fetal myocardial deformation throughout pregnancy

Gepubliceerd: 06-04-2018 Laatst bijgewerkt: 15-05-2024

fetal heart deformation and its development throughout pregnancy can be measured by speckle tracking. Fetal heart deformation might be different in pregnancies complicated by placental dysfunction.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20837

Bron
Nationaal Trial Register

Aandoening

fetal heart deformation
fetal growth restricion
fetal heart development

foetaal hart en de ontwikkeling van de functie van het hart.
foetale groeivertraging

Ondersteuning

Primaire sponsor: Máxima Medical Center, Board of Management
Board of Management Máxima Medical Center (in Dutch: Raad van Bestuur
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In this longitudinal cohort study, the main study parameter is the determination of normal values of fetal myocardial deformation with increasing gestation.

Normal values of fetal myocardial deformation that can be obtained:
Strain (%)
Strain rate (1/strain)
Velocity (cm/s)
Dyssynchrony (ms)
Sphericity index
Shortening fraction (%)

Toelichting onderzoek

Achtergrond van het onderzoek

Pregnant women, pregnant from a singleton, will be asked for a 4-weekly fetal heart ultrasound examination from 19 gestational age untill birth. Women, pregnant from a growth restricted fetus, will be examined on a weekly base from the moment of diagnosis until birth.

A DICOM of the 4 chamber view of the fetal heart wil be performed at every examination. Offline analysis and measurement of fetal heart deformation values per gestational age will be performed. These measurements do not have any cliical implications yet; we study the normal development. In a pilot study we will compade the deformation values from uncomplciated pregnancies with pregnanciees complicated by fetal growth restriction, hypertensive disease or gestational diabetes.

Doel van het onderzoek

fetal heart deformation and its development throughout pregnancy can be measured by speckle tracking.

Fetal heart deformation might be different in pregnancies complicated by placental dysfunction.

Onderzoeksopzet

Pregnant women, pregnant from a singleton, will be asked for a 4-weekly fetal heart ultrasound examination from 19 gestational age untill birth. Women, pregnant from a growth restricted fetus, will be examined on a weekly base from the moment of diagnosis until birth.

Onderzoeksproduct en/of interventie

not applicable; observational study

A DICOM of the fetal heart wil be performed, offline analysis and measuement of fetal heart deformation values per gestational age will be performed. these measurements do not have any cliical implications yet; we study the normal development.

Contactpersonen

Publiek

N.H.M. van Oostrum
Máxima Medical Center (MMC)
De Run 4600

Veldhoven 5504 DB
The Netherlands
+31 40 8888384

Wetenschappelijk

N.H.M. van Oostrum
Máxima Medical Center (MMC)
De Run 4600

Veldhoven 5504 DB
The Netherlands
+31 40 8888384

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Singleton pregnancy

-Age >18 years

-No suspicion of congenital anomalies that coul
d possibly interfere with fetal cardiac function at anomaly scan
-Pregnancies complicated with gestational diabetes (GDM), Fetal growth restriction (FGR) or maternal hypertensive disease, defined as:

GDM:

Hyperglycemia occurring after 20 weeks gestational age. Diagnosis by 75 gram oral glucoses tolerance test; at least one elevated measurement from two measurements taken after fasting > 8 hours followed by 75 gram glucoses taken; first measurement> 7.0 mmol/l and/ or measurement after 2 hours > 7.8 mmol/l

Maternal hypertensive disease, including:

Pregnancy induced hypertension (PIH); systolic blood pressure >140mmHg and/ or diastolic blood pressure >90mmHg occurring after 20 weeks gestational age

Pre-eclampsia (PE): hypertension as defined above and proteinuria (>300mg/24h)

HELLP syndrome: combination of hemolysis (LDH >600 U/L, haptoglobin<0.2g/L, elevated liver enzymes (ASAT or ALAT >70 U/L) and low platelets (<100.109/L), with or without hypertension or PE

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 nog niet gestart
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48690
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6936
NTR-old	NTR7132

Register	ID
CCMO	NL64999.015.18
OMON	NL-OMON48690

Resultaten