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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

## 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<br>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. <br><br>

Normal values of fetal myocardial deformation that can be obtained:<br>
Strain (%)<br>

Strain rate (1/strain)<br>
Velocity (cm/s)<br>
Dyssynchrony (ms)<br>
Sphericity index <br>
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

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## Wetenschappelijk

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# 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 : | Gerealiseerd |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort : | Niet van toepassing |

# Registraties

## In dit register bekende (historische) registraties

Geen registraties gevonden

## In overige registers

| | |
|---|---|
| Source : | NTR |

| Register | ID |
|---|---|
| NTR-new | NL6936 |
| NTR-old | NTR7132 |
| CCMO | NL64999.015.18 |

# Resultaten