# Fetal myocardial deformation throughout pregnancy

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

# **Summary**

# ID

NL-OMON20837

Source NTR

#### **Health condition**

fetal heart deformation fetal growth restricion fetal heart development

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

# **Sponsors and support**

**Primary sponsor:** Máxima Medical Center, Board of Management Board of Management Máxima Medical Center (in Dutch: Raad van Bestuur **Source(s) of monetary or material Support:** not applicable

## Intervention

## **Outcome measures**

#### **Primary outcome**

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

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Normal values of fetal myocardial deformation that can be obtained:

Strain (%)

Strain rate (1/strain)

Velocity (cm/s)

Dyssynchrony (ms)

Sphericity index

Shortening fraction (%)

#### Secondary outcome

Fetal myocardial deformation values in complicated pregnancies (i.e pregnancies complicated with gestational diabetes, fetal growth restriction, maternal hypertensive disease in pregnancy), will be compared to the values in uncomplicated pregnancies in an explorative pilot study.

Inter-and intra-observer variability will be examined and limits of agreement will be assessed. Analysis of the images will be performed offline by 2 different researchers who are blinded for each other's results. All the images will be examined twice by the same examiner, leaving 4 weeks in between the examinations so the examiner will be blinded for the first results.

# **Study description**

#### **Background summary**

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.

#### Study objective

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.

#### Study design

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.

#### Intervention

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.

# Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

-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

## **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

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Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	150
Туре:	Anticipated

# **Ethics review**

Not applicable Application type: Not

Not applicable

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 48690 Bron: ToetsingOnline

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Titel:

# Other (possibly less up-to-date) registrations in this register

No registrations found.

# In other registers

Register	ID
NTR-new	NL6936
NTR-old	NTR7132
ССМО	NL64999.015.18
OMON	NL-OMON48690

# **Study results**