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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.

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

Summary

Health condition

fetal heart deformation
fetal growth restriction
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.

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 until 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 will 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 clinical implications yet; we study the normal development. In a pilot study we will compare the deformation values from uncomplicated pregnancies with pregnancies 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 until 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 will be performed, offline analysis and measurement of fetal heart deformation values per gestational age will be performed. these measurements do not have any clinical implications yet; we study the normal development.

Contacts

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Eligibility criteria

Inclusion criteria

- Singleton pregnancy
- Age >18 years
- No suspicion of congenital anomalies that could 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 glucose tolerance test; at least one elevated measurement from two measurements taken after fasting > 8 hours followed by 75 gram glucose 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)
No intervention arm :	N/A , unknown

Recruitment

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

Ethics review

Not applicable	
Application type :	Not applicable

Study registrations

(Historical) registrations known in this register

No registrations found

In other registers

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

Study results