NI-fECG and STE: 16-28 weeks gestational age.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25988

Source
Nationaal Trial Register

Brief title
BEATS-study

Health condition

HDP, FGR, (Threatened) preterm birth.

Sponsors and support

Primary sponsor: Board of Management Máxima Medical Center
Source(s) of monetary or material Support: Board of Management Máxima Medical Center and Stichting de Weijerhorst.

Intervention

Outcome measures

Primary outcome

Primary outcomes: to determine reference values in pregnancies without PRD for NFMS parameters (e.g. cardiac time intervals, fetal heart rate variability (fHRV), maternal heart rate variability (mHRV), CTG waveform patterns, contraction amplitude, contraction frequency, velocity, entropy) and 2D-STE parameters (e.g. strain, strainrate, velocity, dyssynchrony,

sphericity index, shortening fraction).

Secondary outcome

Secondary outcomes: to explore the diagnostic potential of NFMS and 2D-STE parameters during the second trimester (between 16 and 28 weeks gestational age) to compare these parameters between pregnancies with and without PRD, a prediction model for PRD using NFMS and 2D-STE parameters together with demographics. Additional objectives: association between NFMS parameters and 2D-STE parameters, inter- and intra-observer variability of NFMS and 2D-STE, association between fHRV and mHRV, and the association of ultrasound measurements and actual birthweight to diagnose FGR.

Study description

Background summary

Background: Common complications during pregnancy are hypertensive disorders of pregnancy (HDP), fetal growth restriction (FGR), and premature birth. These complications are important causes of maternal and neonatal mortality and long term morbidity. Pregnancies complicated by HDP are believed to be initiated by placental dysfunction. Placental dysfunction can result in FGR. As a result, the normal growth and development of the fetus and neonate is endangered. In the process of fetal adaptation to placental insufficiency, the fetal heart has a major role. Even subtle cardiac changes would be responsible for a worse perinatal outcome. Threatened preterm birth is likely associated with a change in uterine cell excitability, favoring conduction of electrical activity across the uterine muscles. Ante partum assessment of the cardiac function and uterine activity is therefore essential for the evaluation of pregnancies complicated with a PRD. Even though several diagnostic tools have been used to predict these PRD, unfortunately none of these tests have been successful. Promising new tools in the prediction of the aforementioned pregnancy related diseases (PRD) are the Nemo Fetal Monitoring System® (NFMS) and two-dimensional speckle tracking echocardiography (2D-STE). However, in order to determine PRD, it is first needed to determine physiological changes during pregnancy using the NFMS and 2D-STE. Reference values can then be established in uncomplicated pregnancies. A part of this cohort will develop PRD. The NFMS and 2D-STE parameters of these complicated pregnancies can then be compared with the reference values to investigate whether the PRD can be predicted.

Objective: The primary objective of this study is to generate reference values for NFMS parameters as well as for 2D-STE parameters during the second trimester, 16 until 28 weeks gestational age. The secondary objective is to investigate the diagnostic potential of NFMS parameters and 2D-STE parameters to detect PRD in the second trimester, before they become aberrant, to examine if we can predict pregnancies that are at high risk for PRD at a very early stage of pregnancy using NFMS and / or 2D-STE parameters.

Study objective

NFMS (NIFECG and EHG) parameters are associated with HPD, IUGR and preterm birth and can help detect these diseases during early gestation.

Study design

Fetal heart deformation will be analysed 4-weekly at 16, 20, 24 and 28 weeks gestational age using 2D-STE. NFMS recordings will be made weekly from 22 until 28 weeks gestational age.

Intervention

Longitudinal prospective cohort design. Subjects will be recruited at their first antenatal consultation before 16 weeks gestational age. Fetal heart deformation will be analysed 4-weekly at 16, 20, 24 and 28 weeks gestational age using 2D-STE. NFMS recordings will be made weekly from 22 until 28 weeks gestational age to obtain all parameters of the cardiotocogram (CTG), fetal electrocardiogram, electrohysterogram (EHG) and maternal electrocardiogram. Data will be analysed using specified software. Follow-up ends 6 weeks after delivery.
Population: Pregnant women with a singleton pregnancy at 16 weeks gestational age will be included to the prospective cohort. Retrospectively, the PRD group (women who develop a PRD from the start of the measurements until birth) will be compared with the healthy control group. PRD is defined as: HDP, FGR and preterm birth.

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Eligibility criteria

Inclusion criteria

- Pregnant women with a singleton pregnancy;
- Uncomplicated pregnancy at the time of inclusion;
- Gestational age <16+0 weeks;
- Oral and written consent is obtained;
- Maternal age ≥ 18 years.

Exclusion criteria

- Multiple pregnancies;
- Pre-existing maternal disease that might influence fetal development (e.g. diabetes mellitus, pre-existent hypertensive disease or auto-immune disease); - Abnormalities found at the structural ultrasound examination (SEO) that might possibly influence fetal cardiac function (e.g. fetal cardiac arrhythmias or congenital abnormalities);
- Contra-indications to abdominal patch placement (e.g. dermatologic diseases of the abdomen precluding preparation of the abdomen with abrasive paper); - Women connected to an external or implanted electrical stimulator (e.g. a pacemaker);
- Insufficient ability in understanding Dutch or English language;
- Patient under the age of 18 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	594
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	26-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8769
Other	METC MMC : W20.076

Study results