Cardiac Performance Index using 'Region Of Interest Tissue Doppler Imaging (ROI-TDI)';
a new parameter for fetal myocardial performance

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The primary objective of this study will be to investigate reproducibility of ROI-TDI for fetal cardial performance in a group of normal pregnancies, and compare this new proposed parameter with the Myocardial Performance Index. The data will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40732

Source
ToetsingOnline

Brief title
ROI-TDI in fetal cardiac performance

Condition

- Congenital cardiac disorders

Synonym
Myocardial performance

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Toshiba

Intervention

Keyword: color-TDI, Fetal heart, Myocardial performance

Outcome measures

Primary outcome

The main study parameter of this study is the new parameter for fetal cardial

performance using ROI-TDI with MPI

Secondary outcome

Secundary outcome is to generate normal values for the new parameter in a

group of normal pregnancies.

Study description

Background summary

Congenital heart disease is the most common disorder found in new-borns. With upcoming techniques for fetal echocardiography antenatal detection rate is rising, but still a reproducible technique for fetal heart function is not available. Myocardial Performance Index (MPI) generated from pulsed wave Doppler is the most used parameter to define fetal cardiac function, but is limited because of the high interobserver variability.

Color Tissue Doppler Imaging (TDI) and Speckle Tracking in the Foetal heart is a relatively new and promising technique in foetal diagnostic echocardiography, but has been reported with various results and seems not routinely applicable with limited frame rates (30Fr/s). Toshiba Aplio provides Raw Data Storage with acoustic Frame rates (>100Fr/s) to allow a higher spatial resolution and probably more accurate detection. Using Speckle Tracking a new proposed parameter for cardial performance can be extracted with a higher reproducibility and lower inter and intraoberserver variability, and therefore be an aid in early detection of fetal cardiac dysfunction.

Study objective

The primary objective of this study will be to investigate reproducibility of ROI-TDI for fetal cardial performance in a group of normal pregnancies, and compare this new proposed parameter with the Myocardial Performance Index. The data will be used as well to generate normal values for the new performance parameter, and define the minimum duration of gestation for ROI-TDI approach.

Study design

Longitudinal prospective approach.

Participating women will receive a short ultrasound examination 4-5weekly (10 minutes), starting from 16 weeks of gestational age up to the third trimester, in total 4 exams will be done. These ultrasounds will be focused on cardiac function including a color-TDI clip of 2,5 seconds, and fetal biometry. Measurements will be generated off line at a later stadium.

Study burden and risks

Extra ultrasound examinations are performed 4-5 weekly in the LUMC. Except for the time needed for the exam , this study does not add interventions, so no additional risks are present. Patient data needed for analysis will be withdrawn from the patient file, no questionnaires are added. Our study will not influence the standard care. All patients are free to participate or to exit the study at any moment during the study time.

A benefit for an individual woman is only of emotional character, the extra ultrasound will provide the patient an echographic follow-up of her unborn child and she will receive representative images after each ultrasound.

This study will contribute to find better antenatal parameters in measurement of cardiac performance in foetuses. In the future, having better parameters for cardiac performance might contribute to better prenatal care in pregnancies where intervention might be needed for example when myocardial performance of the foetus deteriorates, for example in cases of TTTS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Maternal age over 18 years
- Singleton uncomplicated pregnancy
- ability to give informed consent

Exclusion criteria

- Maternal diabetes
- Maternal hypertension / pre eclampsia
- Chromosomal or major congenital anomalies of the fetus
- Cardiac abnormalities of the fetus

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL50078.058.14