Fetal echocardiography using Spatiotemporal Image Correlation (STIC). In vitro validation and examination of the fetal cardiac anatomy and function.

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We will investigate the feasibility of using STIC technology to evaluate the fetal cardiac anatomy in different stages of gestation. Further we will investigate the fetal cardiac function using STIC technology.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON30103

Source
ToetsingOnline

Brief title
FESTIC, validation, anatomy and function.

Condition

- Cardiac and vascular disorders congenital
- Foetal complications

Synonym
fetal heart function, heart anatomy, pump function of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: geen kosten

Intervention

Keyword: 4-dimensional., echocardiography, fetal cardiac function, Spatiotemporal image correlation

Outcome measures

Primary outcome

We will investigate the feasibility of using STIC technology to evaluate the

fetal cardiac anatomy in different stages of gestation. Further we will

investigate the fetal cardiac function using STIC technology.

Secondary outcome

not applicable

Study description

Background summary

Congenital heart malformations represent the most common severe congenital disease. The prevalence ranges from 4 to 8 cases per 1000 live births.(1) Therefore the fetal heart is the subject of major screening programs aiming to detect cardiac malformations in an early stage of pregnancy. Nevertheless, cardiac anomalies are the most commonly overlooked lesions and many efforts have been made to increase the detection rate of congenital heart malformations. Another area that has received much attention is the evaluation of cardiac function to evaluate fetal well being.
Spatio-temporal image correlation (STIC) is the latest ultrasonographic approach to clinical assessment of the fetal heart. STIC is an automated volume acquisition, recording one single three-dimensional volume dataset. The cardiac volumes are then displayed as one real-time cardiac cycle, played in a cine-loop. This loop can be played in slow motion or stopped at any time for analysis and because there is a volume dataset, each of the scan planes can be moved and rotated while maintaining the synchronized cardiac loop. These possibilities give STIC technology the potential to increase detection rates

for congenital heart malformations.
Conventional ultrasound techniques together with techniques such as M-mode and pulsed doppler have been used to estimate fetal cardiac function.
Two-dimensional and M-mode ultrasound- based studies have established a range of cardiac dimensions in the normal and abnormal heart. For cardiac volume calculations both 2D and M-mode ultrasound, however, have their limitations. Because STIC technology gives the investigator the opportunity to freeze the three-dimensional cardiac loop in end-diastolic and end-systolic phase, more accurate volume measurements can be used to calculate fetal heart stroke volume, cardiac output and ejection fraction based on 3D volume measurements.

Study objective

We will investigate the feasibility of using STIC technology to evaluate the fetal cardiac anatomy in different stages of gestation. Further we will investigate the fetal cardiac function using STIC technology.

Study design

In this prospective longitudinal study STIC volume datasets will sequentially be collected every four weeks from healthy fetuses with gestational age ranging from 11 to 24 weeks.

STIC volumes will be scored on their ability to display different cardiac structures used to evaluate cardiac anatomy. All displayed structures are scored on a scale of 1 to 5, based on their visualization and image quality.

We will create normograms for stroke volume, ejection fraction and cardiac output based on 3D volume measurements of right and left ventricular volume in systole and diastole.

Also an in vitro validation of volume measurement using STIC will be preformed.

Study burden and risks

Ultrasound has been used in obstetrics since the 1970's. There are no proven adverse effects of ultrasound investigations on foetus or mother.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

singleton pregnancies with confirmed pregnancy dates by first trimester ultrasound.

Exclusion criteria

Twin pregnancies, unconfirmed pregnancy dates, congenital heart malformations

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12232.029.06