Fetal echocardiography using Spatiotemporal Image Correlation (STIC) for the detection of congenital heart malformations (CHD).

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1. To investigate whether examination of STIC volumes give an investigator more information about the cardiac anomaly compared to 2D ultrasound.2. To evaluate the reproducibility of fetal heart examinations of STIC volumes by different investigators...

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

Summary

ID

NL-OMON30097

Source
ToetsingOnline

Brief title
FESTIC, congenital heart malformations

Condition

- Congenital cardiac disorders

Synonym
Congenital heart disease, heart malformation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: geen kosten aan onderzoek verbonden

Intervention

Keyword: 4 dimensional, congenital heart malformations, fetal echocardiography, Spatiotemporal Image Correlation (STIC)

Outcome measures

Primary outcome

To compare conventional 2D echocardiography with 4D echocardiography to display

different anatomical structures in congenital heart malformations.

Secondary outcome

not applicable

Study description

Background summary

Congenital heart malformations represent the most common severe congenital disease. Approximately 8 out of 1000 babies are born with congenital heart malformations. 1 Nevertheless cardiac anomalies are the most commonly overlooked lesions. Prenatal diagnosis of congenital heart malformations allows planning and delivery of timely and appropriate neonatal care.
Real-time 2D ultrasound, the routinely-used tool for fetal echocardiography, is a sophisticated diagnostic method but it remains limited. The technique is very operator-dependent and is commonly time consuming. The addition of imaging the right and left outflow tracts to fetal heart examination has increased the detection of cardiac defects, but the detection rate of isolated congenital heart malformations still remains low.
Spatio-temporal image correlation (STIC) is the latest approach to clinical assessment of the fetal heart. STIC is an automated volume acquisition in which the array inside the transducer housing performs a slow, single sweep, recording one single three-dimensional volume dataset. Echocardiography using new STIC technology may have the potential for making the echoscopic screening for congenital heart malformations less operator-dependent and may increase the prenatal detection rate for congenital heart defects.
No studies however have systematically investigated the feasibility and capability of STIC technology to perform a full cardiac examination when cardiac anomalies are suspected and compared this with convertional 2D

echocardiography. Another field that is not yet has been studied is the reproducibility of an echocardiographic assessment using STIC technology.

Study objective

1. To investigate whether examination of STIC volumes give an investigator more information about the cardiac anomaly compared to 2D ultrasound.
2. To evaluate the reproducibility of fetal heart examinations of STIC volumes by different investigators.

Study design

1. During and ultrasound investigation when cardiac anomalies are suspected, multiple STIC volume datasets are acquired from fetuses with different CHD with gestational age ranging from 11 to 40 weeks. Before acquisition of a STIC volume a full 2D cross-sectional echocardiographic examination is preformed by one experienced sonographer. During the 2D echocardiographic examination a listed number of anatomical structures are scored on their visibility. The STIC volumes are examined off-line and are also scored on their ability to display the listed cardiac anatomic structures when present. For the ability to visualize the cardiac structures percentages are calculated to compare the two forms of fetal cardiac examination

2. From a digital database containing STIC volume datasets volumes of twenty fetus are selected with congenital heart defects. For each fetus two volume datasets of sufficient quality are selected for review by one investigator. Then the volumes are randomly assigned for a blinded review to three independent investigators. All of the investigators are experienced in fetal echocardiography and all will receive a training in the use of the software used to examine the volumes off-line. All investigators will diagnose the present CHD or exclude the existence of CHD for all twenty fetus examined. The results of all three investigators are compared to examine inter-investigator reproducibility of cardiac diagnoses using STIC technology.

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

Pregnant women carring a foetus with a suspected congenital heart malformation, confirmed pregnancy dates, singleton pregnancies

Exclusion criteria

Twins. unconfirmed pregnancy dates

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:	95
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	NL12277.029.06