Comparison of prenatal and postnatal cardiac function assessed by echocardiography using pulsed wave Doppler, Tissue Doppler and speckle tracking (strain and strain rate) between foetuses/neonates with a structural heart disease, with an fetal growth restriction (FGR) and healthy fetuses/neonates

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON53531

Source
ToetsingOnline

Brief title
STIPP-study

Condition

- Heart failures
- Cardiac and vascular disorders congenital

- Neonatal and perinatal conditions

Synonym
Structural heart disease (congenital heart defect). Fetal growth restriction.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: Cardiac function, Fetuses, Neonates, Speckle tracking

Outcome measures

Primary outcome

Comparison of fetal systolic and diastolic function in fetuses with a structural heart disease, fetuses with an FGR and healthy fetuses, using (blood) speckle tracking, pulsed waved Doppler and tissue Doppler, at multiple time points in the pregnancy and within 72 hours postpartum.

Secondary outcome

Technical feasibility of cardiac function measurements by means of fetal echocardiography using speckle tracking, pulsed waved Doppler and tissue Doppler in fetuses with a structural heart disease. This includes the comparison of two software*s used to evaluate cardiac deformation (TOMTEC and Voluson Fetal HQ) by speckle tracking and the additional value of fetal electrocardiogram during cardiac function measurements and the optimization of the used techniques.

Study description

Background summary

Currently, fetal echocardiography mainly focusses on the detection of structural heart disease. New echocardiographic techniques also permit detailed assessment of the myocardial contraction and relaxation, permitting early detection of subtle changes in heart function. Structural heart disease and fetal growth restriction are often accompanied by changes in myocardial function. These changes already start during early intrauterine life. They can influence clinical course and outcome during fetal adaptation to hypoxic intrauterine conditions, during transition from fetal to neonatal circulation and during early neonatal life in both growth restricted infants and infants with heart disease. With improved survival of these infants, it becomes clear that these changes in cardiac function, subtle in early life, often progress or induce remodelling affecting long term cardiovascular outcome. Expanding the ultrasonic examination of the heart by adding measurements related to fetal cardiac function would increase knowledge about the physiology and pathophysiology of cardiac adaptation during fetal and early neonatal life in healthy infants as well in infants with fetal growth restriction and/or a structural heart disease.
Early detection of dysfunction could lead to targeted preventive strategies to improve short term and long term cardiovascular outcomes in these vulnerable children.

Early changes before overt cardiac dysfunction can be observed by analysing myocardial deformation during contraction and relaxation with ultrasonic techniques such as (blood) speckle-tracking (focussing on myocardial strain and strain rate) and Tissue Doppler. These techniques are validated in the adult and pediatric populations but remain experimental in fetuses. The fetal heart is much smaller, beats faster and is more difficult to assess through the maternal abdomen. Besides that, the circulation and balance between left and right ventricle is fundamentally different in a fetus. This brings challenges in technical feasibility as well as in clinical interpretation of differences. Recent technical innovations permit to overcome the former and gain experience with the latter.

Along with 2-D, 3-D and pulsed waved Doppler assessments, inclusion of these techniques could be of additional value in the assessment of the fetal heart.

Study objective

Comparison of prenatal and postnatal cardiac function assessed by echocardiography using 2-D, 3-D, pulsed wave Doppler, Tissue Doppler and (blood) speckle tracking (focussing on strain and strain rate) between fetuses/neonates with structural heart disease, fetuses/neonates with fetal

growth restriction (FGR) and healthy fetuses/neonates, both prenatally and postnatally.

Study design

A longitudinal prospective cohort study, conducted at the Department of Obstetrics and Gynaecology (Division of Fetal Medicine) and the Department of Paediatrics (Division of Paediatric Cardiology and Division of Neonatology) of the Erasmus Medical Centre Rotterdam.

Study burden and risks

Burden associated with participation exists for the group with healthy fetuses of two (additional) prenatal investigations and one (additional) postnatal investigation. For the group with fetuses with a structural heart disease the burden exists of one (additional) prenatal investigation and for the group of fetuses with a growth restriction, the burden exists of one (additional) postnatal investigation. All investigations have an estimated time of 15-30 minutes. Ultrasound can be safely used in pregnancy (Doppler ultrasound can be safely used from 11 weeks in pregnancy). There is no risk associated with participation for mother and fetus. There is no individual benefit for participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- Informed consent - Sufficient command of the Dutch language - A pregnancy with a fetus with a structural heart disease, or - A pregnancy with a fetus with an FGR (defined as: weight and/or abdominal circumference p<10, or deviating growth (weight and/or abdominal circumference) > 20 percentiles, and Doppler abnormalities in either the umbilical artery, the uterine artery or the medial cerebral artery), or - A pregnancy with a healthy fetus (without any major fetal congenital abnormality)

Exclusion criteria

- Multiple pregnancy
- A pregnancy with known fetal genetic abnormality
- A pregnancy with other major fetal congenital abnormalities

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2022
Enrollment:	201
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCTnummervolgt.
CCMO	NL80033.078.21