Fetal development of the left ventricular myocardium in left sided congenital heart defects

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

Summary

ID

NL-OMON45878

Source
ToetsingOnline

Brief title
DEMY (DEvelopment of the left ventricular MYocardium in utero)

Condition

- Congenital cardiac disorders

Synonym
Aortic narrowing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Development, Fetus, Left ventricle, Myocardium

Outcome measures

Primary outcome

Measurements to assess myocardial development and function:

- Global longitudinal strain of the left ventricle obtained by speckle tracking

Secondary outcome

Measurements to assess myocardial development and function:

- Speckle tracking measurements: global longitudinal strain of the right ventricle, global longitudinal strain rate of the left and right ventricle, global longitudinal velocity in left and right ventricle, regional strain analysis (basal septal, mid septal, apical septal, apical lateral, mid lateral, basal lateral).

- cTDI measurements: left ventricle shortening, left ventricle lengthening, inter shortening-lengthening time, inter lengthening-shortening time.

Study description

Background summary

Aortic coarctation (CoA) is a life-threatening cardiac defect which frequently requires surgery in the first year of life. CoA comprises 5-8% of all congenital heart defects. Prenatal diagnosis is critically important, as timely management with prostaglandins after birth reduces neonatal morbidity and mortality in severe cases. Prenatal identification of CoA is, however, challenging. Ventricular and semilunar valve size disproportion with a smaller left side on fetal ultrasound are known predictors of CoA, but sensitivity is moderate and specificity is low. The high false-positive rate can be attributed to the fact that distinction between a pathological ventricular size disproportion and normal physiological right-sided dominance is difficult,

especially late in gestation. False-positive diagnosis may result in parental anxiety and unnecessary neonatal intensive care admissions immediately after birth.

Prenatal detection of more severe cases (significant ventricular disproportion or aortic arch hypoplasia) is easier since these fetuses have dramatically altered ultrasonographic findings. In these cases, however, it is difficult to predict the left ventricular development in time. Parents and health care providers are faced with the uncertainty whether the left ventricle of the fetus will reach a sufficient size to support the systemic circulation after birth. Some cases may develop hypoplastic left heart syndrome (HLHS), a condition with high morbidity and severity.

Over the past decade, most studies have focused on the improvement of prenatal detection of CoA. However, the underlying pathophysiology why cases with similar ultrasonographic appearance develop differently is still not fully understood. Differences in fetal myocardial development and morphology, leading to differences in myocardial function and deformation, could play a role. Tools to assess fetal myocardial development comprise new ultrasonographic techniques like color Tissue Doppler Imaging (cTDI) and speckle-tracking.

We hypothesize that the left ventricle shows a different myocardial development and function with as a result an altered blood flow pattern in fetuses with a CoA, compared to fetuses that turn out not to have CoA postnatally. This knowledge could contribute to a better prediction, necessary for proper counselling.

Study objective

The primary aim is to assess myocardial development and function of the left ventricle in fetuses with the suspicion of aortic coarctation on fetal echocardiography.

The secondary aim is to study left ventricular blood flow movement with vector analysis in these cases.

Study design

We will conduct a single-center, non-randomized, prospective, observational case-control study. All pregnant women with the antenatal suspicion of aortic coarctation on fetal echocardiography will be selected. Subjects will be followed during pregnancy and allocated to either cases or controls after birth, according to the postnatal diagnosis and need for intervention:
- Cases: fetuses with postnatally confirmed CoA in need of an aortic arch repair.
- Controls: fetuses with a physiological right-sided dominance of the fetal

heart: no need of a coarctation repair operation after birth.
Cases and controls will be matched for gestational age. All fetal ultrasound examinations are conducted by experienced ultrasonographers (A.K.K. Teunissen, physician-ultrasonographer, and F.Zwanenburg, primary investigator) at the Leiden University Medical Center (LUMC), under supervision of M.C. Haak, consultant in fetal medicine.

Study burden and risks

Ultrasound is a safe and non-invasive technique, which means that both mother and fetus are not exposed to additional risks in pregnancy or after birth.
Since the only difference by participating in this study will be the additional cardiac measurements performed during routine echocardiographic examinations, the burden to participate is considered negligible. Participants do not have benefits of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant women with:
- suspicion of CoA on fetal ultrasound:
* ventricular size disproportion (right to left ventricle ratio >1.3) and/or,
* great arterial size disproportion (pulmonary to aorta artery ratio >1.3) and/or,
* aortic arch hypoplasia
- age >=18 years of age
- 18-34 weeks of gestational age
- singleton or dichorionic twin pregnancy

Exclusion criteria

- Fetal or neonatal diagnosis of other structural defects which could influence myocardial function, except for cardial defects leading to CoA. Cases with a premature closed foramen ovale, persistent vena cava superior sinistra, bicuspid aortic valve or small ventricular septum defect will be included as these conditions are common in CoA.
- Fetal chromosomal abnormalities identified by diagnostic testing
- Monochorionic twin pregnancy

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:	Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	17-01-2019
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	14-01-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL66978.058.18