Advanced Fetal MRI techniques: assessment of fetal cardiovascular anatomy disturbances in children with congenital heart disease

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

Summary

ID

NL-OMON56891

Source
ToetsingOnline

Brief title
Future 2.0

Condition

- Cardiac and vascular disorders congenital

Synonym
Complex congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Stichting Hartekind

Intervention

Keyword: Cardiovascular, Congenital Heart disease, Fetal, MRI

Outcome measures

Primary outcome

To test feasibility of fetal CMR on the three available MRI vendors (Philips,

Siemens, General Electric) in all academic centers in The Netherlands.

Secondary outcome

To assess diagnostic capacity of fetal CMR and the additive value to fetal

echocardiography (at gestational age 20-24 weeks and 30-34 weeks) for correct

antenatal diagnosis of significant aortic and/or pulmonary CHD (correct CHD

diagnosis based on postnatal findings).

Study description

Background summary

Congenital heart disease (CHD) is the most common of all major congenital anomalies and affects around 9 out of 1000 live births. Mortality rates have been reduced, but CHD is still the second most frequent cause of neonatal death2. Fetal echocardiography has significantly improved antenatal diagnosis of CHD, but limitations remain. Discordance between pre- and postnatal diagnosis of CHD has been described, with impact on neonatal management. Especially vascular anomalies such as coarctation of the aorta, have proven to be difficult to detect and predict by fetal echocardiography. Therefore, there is a clinical need for a complementary imaging modality to further improve the current fetal diagnostic work-up of CHD, for which recently developed fetal cardiovascular magnetic resonance imaging (CMR) may be suited.

Hypothesis: Fetal CMR may improve the diagnostic accuracy of prenatal diagnosis of CHD when compared to fetal echocardiography in The Netherlands.

Study objective

The primary research objective is to assess the feasibility of fetal CMR in all academic centers in The Netherlands.
The second research objective of the study is to investigate the diagnostic capacity of fetal CMR for aortic and pulmonary CHD and the additive value to fetal echocardiography (at gestational age 20-24 weeks and 30-34 weeks) for correct antenatal diagnosis of CHD.

Study design

Prospective cohort study of expectant mothers of fetuses with significant aortic and/or pulmonary CHD undergoing fetal CMR and fetal echocardiographic evaluation.

Study burden and risks

The burden for both the mother and the fetus is the experience of undergoing fetal CMR,. Fetal CMR can be performed within 30/45 minutes of scan time, which can be difficult for a mother in her third trimester of pregnancy. Therefore, specific attention will be paid to the mother*s condition, as she will be positioned in a comfortable position and with left lateral tilt, to prevent vena cava inferior syndrome, and hearing protection will be offered. Fetal MRI for other purposes such as fetal brain imaging is performed in most participating institutions, which facilitates the introduction of fetal CMR. Current experimental and clinical evidence indicates that there are no adverse biological effects for pregnant women, fetuses and neonates from the use of CMR14,15. MRI vendor differences between the participating institutions (Philips, Siemens and General Electric) will be overcome by support of our two study MRI physicists and by an international scientific advisory committee with ample experience in fetal CMR. The post-processing techniques are considered to be generic and applicable/compatible to all available MRI systems in the participating centers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Antenatal diagnosis of significant aortic and/or pulmonary CHD, defined as requiring intervention within the first year of postnatal life.
Informed consent provided by both parents.
Gestational age >24 weeks. The optimal gestational age for fetal CMR currently lies between 30-34 weeks.

Exclusion criteria

Maternal age <16 years
Inability to correctly inform parents about study due to language barrier or other factors
Contraindication to MRI (see Radiology department checklist)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2025
Enrollment:	159
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-03-2025
Application type:	Amendment
Review commission:	METC NedMec

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	NL86052.041.24