Four dimensional flow analysis of complex congenital heart disease

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To determine whether 4D-flow CMR volume measurements are superior to 2D-PC CMR volume measurements by comparing the intra-class correlation between 2D-PC flow CMR stroke volume measurements in the MPA and multi-slice volumetric RV flow volume to the...

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

Summary

ID

NL-OMON48789

Source
ToetsingOnline

Brief title
VELOCITY

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
arterial switch circulation, Transposition of the great arteries

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Hartekind

Intervention

Keyword: Arterial Switch Operation, Congenital heart disease, Transposition of the Great Arteries

Outcome measures

Primary outcome

* The ICC of 2D-PC CMR stroke volume measurements in the MPA and multi-slice

volumetric RV flow volume

* The ICC of 4D-flow CMR measurements in the MPA and multi-slice volumetric RV

flow volume measurements

Secondary outcome

o Net flow (mL/cycle)

o Retrograde flow (%)

o Peak flow (mL/s)

o Time-to-peak flow (ms)

o Peak acceleration (L/s^2)

o Resistance index

o Wall shear stress (Pa).

o Pressure difference (mmHg).

o Pulse wave velocity (m/s).

o Turbulent kinetic energy (mW).

o Viscous energy losses (mW).

o Peak velocity (m/s).

Study description

Background summary

In children born with a transposition of the great arteries the aorta arises from the morphologic right ventricle and the pulmonary artery arises from the morphologic left ventricle. The right ventricle pumps oxygen-poor blood from the body into the aorta and to the rest of the body, while the left ventricle pumps oxygen-rich blood coming from the lungs back into the pulmonary artery and to the lungs. This means that, apart from the lungs, there is no supply of oxygen-rich blood to any other organ in the body.

With an arterial switch operation the aorta and pulmonary artery are connected to the 'correct' ventricles. This surgical technique has been performed in Utrecht since 1977. The surgery greatly improves the survival of patients with a transposition of the great arteries. Nonetheless, as they grow older, many patients experience complications. The most common being narrowing of the pulmonary artery and its branches. Often (re)intervention is required. The different underlying pathophysiological processes of these complications is known, However, the effects on the right ventricular function, exercise capacity and lung capicity are still unknown.

The novel, four-dimensional flow cardiac magnetic resonance (4D-flow CMR) technique allows for a more comprehensive evaluation of the pulmonary artery flow, including the site of possible stenosis. 4D Flow CMR provides a non-invasive method for the qualitative and quantitative characterization of blood flow and can be used to derive advanced hemodynamic measures without radiation burden.

We want to qualify and quantify the blood flow in the arterial switch circulation using 4D-flow CMR and investigate whether there is a relationship between abnormal blood flow and clinical outcomes such as right ventricular function, lung function, and exercise capacity.

Study objective

To determine whether 4D-flow CMR volume measurements are superior to 2D-PC CMR volume measurements by comparing the intra-class correlation between 2D-PC flow CMR stroke volume measurements in the MPA and multi-slice volumetric RV flow volume to the intra-class correlation between 4D-flow CMR stroke volume measurements in the MPA to multi-slice volumetric RV flow volume.

The secondary objective is to explore the predictive value of 4D-flow measurements for clinical outcomes such as right ventricular function, exercise capacity and lung function.

Study design

A cross-sectional observational study

Study burden and risks

Participants < 16 years of age:
All diagnostic tests that will be performed are regular follow up investigations. 4D-flow and exercise measurements during CMR are done purely for research purposes. The extra MRI measurements will extend the CMR duration with approximately 10-15 minutes . We will try to plan all three tests on one day.

Participants > 16 years of age:
The echocardiography will be performed as a regular follow up investigation. The CMR and cardiopulmonary exercise test can be performed solely for the study. Both the CMR and the cardiopulmonary exercise test have a duration of approximately one hour. We will plan these investigations on one day, to minimize patient burden. The 4D-flow CMR measurements have no additional risk. The risk of an adverse reaction to the CMR contrast is irrelevant for the study, since administration of contrast will only be done if the treating clinician orders it and not for study purposes. In very rare cases, ventricular tachycardia can develop during cardiopulmonary exercise testing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients < 16 years of age:
- Patients with a transposition of the great arteries who underwent an arterial switch operation
- Patients aged > 7 years
- Patients with a clinical indication for CMR, echocardiography and cardiopulmonary exercise
testing per order of the treating clinician

Patients > 16 years of age:
- Patients with a transposition of the great arteries who underwent an arterial switch operation
- Patients aged 16-40 years

Exclusion criteria

Minors under the age of 8 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-07-2020
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	NL62666.041.17