4D flow hemodynamics in the great arteries in children and adults after arterial switch operation for transposition of the great arteries

Published: 26-08-2015
Last updated: 14-04-2024

1. The application of 4D flow MR imaging to analyse blood flow patterns (flow angle, flow asymmetry), regional vessel wall parameters (regional wall shear stress, vessel wall thickness) and pulsed-wave velocity in neoaortic root, carotid artery and…

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

Summary

ID

NL-OMON42018

Source
ToetsingOnline

Brief title
4D flow MRI in TGA patients

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Aneurysms and artery dissections

Synonym
transposition of the great arteries

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: aorta hemodynamics, blood flow, magnetic resonance imaging, transposition of great vessels

Outcome measures

Primary outcome

1. measurements 2D large vessels:

- LV-ascending aorta outflow angle

- aortic arch angle,

- volume aortic sinus

- aortic wall thickness at predefined anatomical landmarks in the thoracic aorta

- pulmonary artery dimensions (at level of neoaortic root)

2. measurements 4D flow large vessels:

- qualitative:

o identify complex flow patterns, viewed dynamically in 3D: discriminate helix

and vortex flow patterns and localisation of these patterns in the aorta

- flow quantification:

o symmetry/asymmetry of (peak) bloodstream profiles in ascending aorta and

pulmonary arteries

o peak systolic regional wall shear stress at predefined anatomical landmarks

in the thoracic aorta

o 3D pressure difference maps

o turbulent kinetic energy, energy loss

3. measurements of cardiac function:

- end-systolic left ventricle volume

- end-diastolic left ventricle volume

- ejection fraction left ventricle

- regional wall motion disturbances

4. measurements of aerobic fitness:

- oxygen uptake (ml/kg/min)

- peak power in last half minute of graded bicycle ergometer test (Watt)

5. Impedance cardiography parameters:

- estimated stroke volume

- cardiac autonomic control measures

Secondary outcome

None

Study description

Background summary

Transposition of the great arteries (TGA) is one of the most common cyanotic congenital heart diseases. With a prevalence of 3.45 per 10000 live births in Europe, it is the fourth most common type of major cardiac defect, representing 5% of all congenital heart diseases. Uncorrected children with TGA have no change to survive.
The first successful arterial switch operation (ASO) for correction TGA was

performed by Jatene in 1975. From the mid 1980s the ASO became routine and currently the ASO is the operation of choice in the majority of patients with TGA. The procedure involves translocation of the pulmonary artery and aorta above the level of the sinuses and re-implantation of the coronary ostia in the neoaorta. As a result the original pulmonary valve and proximal main pulmonary artery become the neoaortic valve and proximal neoaorta.
Despite excellent early and long-term survival, important residual lesions are increasingly recognized, including dilation of the neoaortic root, neoaortic valve regurgitation, pulmonary arterial stenosis, coronary problems and progressive left ventricular dysfunction. All these factors have been correlated to diminished exercise capacity and reoperations and catheter-based interventions are required 15-20% of patients after ASO during long-term follow-up, till now.

Neoaortic dilation is present in the majority of children and adult patients after ASO. The aortic root dilation is progressive even in adulthood up to 35 years after ASO, with potential complications as neoaortic valve regurgitation, pulmonary artery branch stenosis and development of an acute angle of the coronary origin, resulting in ostial stenosis, increased risk of coronary kinking or wedging of the coronary arteries between the great vessels. Obviously, neoaortic root pathology plays a central role in the management of patients with TGA during follow-up after ASO and concerns are being expressed about the increased need for aortic root reoperation in future. Besides dilation, alterations in intrinsic vessel characteristics, e.g. reduced elasticity and increased stiffness have been observed in this patient population. All these changes can impair left ventricular function.

A second important factor for the preservation of adequate left ventricular function and preservation of normal exercise capacity is an optimal coronary circulation. In a certain percentage of the patients after ASO problems in myocardial perfusion due to coronary problems are seen, even in asymptomatic patients of all ages. Coronary re-implantation at a young age, progressive aortic root dilation and aortic stiffness over time are potential risk factors for development of myocardial tissue alterations (scarring/fibrosis) and secondary left ventricular dysfunction.

The application of 4D flow can provide new insights in the pathogenesis of the development of aortic root pathology in children with TGA. Furthermore, these hemodynamic flow assessments can be used to study the interaction of the enlarged neoaortic root and pulmonary flow patterns as branch pulmonary artery stenosis is a common problem which often requires reoperation and catheter-based interventions after ASO for TGA. In particular, 4D flow in combination with dobutamine induced stress imaging to evaluate the dynamic effect of the expansion of the neoaortic root with increasing stroke volumes on pulmonary artery dimensions and pulmonary flow patterns. Also of special interest are the effects of dobutamine stress on aortic flow profiles, aortic wall shear stress and wall distensibility in relation to the systolic and

diastolic cardiac function (e.g. ventriculo-arterial interaction).

The etiology neoaortic root pathology is not clear and research on these pathophyological mechanisms leading to neoaortic root dilatation (with 4D MRI) and the evaluation of myocardial function and early myocardial tissue alterations are essential for these patients to prevent them from cardiovascular problems in future.

Study objective

1. The application of 4D flow MR imaging to analyse blood flow patterns (flow angle, flow asymmetry), regional vessel wall parameters (regional wall shear stress, vessel wall thickness) and pulsed-wave velocity in neoaortic root, carotid artery and distal aorta in TGA patients after ASO and age-matched controls.
2. To study the static and dynamic influence of aortic root dilation in rest and especially with dobutamine stress on neopulmonary blood flow profiles using 4D flow MR imaging.
3. To study the role of aortic flow hemodynamics in relation to aortic root dilation and geometry in patients after ASO for TGA based on conventional MRI and 4D flow MR imaging.
4. To evaluate and compare the ascending aorta flow hemodynamics in TGA patients after ASO with tricuspid and bicuspid neoaortic valves using 4D flow MR imaging.
5. To evaluate cardiac reserve, left ventricular function and left ventricular myocardial alterations with dobutamine stress CMR in comparison to exercise capacity levels and impedance cardiography parameters.

Study design

Cross-sectional cohort study. Inclusion of 67 patients after arterial switch operation for transposition of the great arteries (TGA) and 60 healthy volunteers of same age. From the 67 TGA patients, 60 patients will have a tricuspid neo-aortic valve, 7 patients will have bicuspid neo-aortic valve (no more patients with bicuspid neo-aortic valve available in the CAHAL cohort). All patients underwent an cardiac MRI (including dobutamin stress imaging), echocardiography, ambulatory 24-hour holter (including impedance cardiography) and an exercise capacity test with investigation of oxygen uptake and work load. Healthy volunteers (over 12 years of age) will underwent same MRI protocol with exclusion of dobutamin stress imaging. No exercise capacity testing and 24-hour holter will be done in the healthy volunteers due to the existence of good reference values.

Study burden and risks

All clinical examinations are the same as are routinely performed during

follow-up of patients operated for transposition of the great arteries, except for dobutamine stress and 4D flow imaging during MR examination, resulting in extra scanning time: two times 15 minutes. For the nature and extent of the burden and risks associated with these investigations I would like to refer you to the answers on the question of items E2, E9, E9a and E10 of this document.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

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 with surgical repair for transposition of the great arteries (TGA) through arterial switch operation.

- Patients operated in the LUMC with clinical follow-up in the CAHAL (Center for Congenital Heart Disease Amsterdam-Leiden) are eligible for inclusion.
- Patients older than 8 years of age.
- Healthy volunteers older than 12 years of age.

Exclusion criteria

Patients with pre-existing arch anomalies at presentation (e.g. aortic coarctation, hypoplastic aortic arch, aortic arch interruption) or those who had undergone a two-stage repair (e.g. previous pulmonary arterial banding before second-stage ASO) will be excluded from inclusion.
Patients with claustrophobia, mental retardation, pacemaker dependency, will not be included in this study.
Excluding factors will be: diagnosis of a chronic disease.

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):	16-12-2015
Enrollment:	127
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2015
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	NL52047.058.15