Hemodynamic characterization of cardiac disease and aortopathy after valve sparing aortic root replacement, mechanical aortic valve implantation or septal myectomy: a 4D-flow MRI study

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- investigate blood flow patterns and energy loss due to viscous dissipation or turbulent kinetic flow in the aorta in patients with aortic root grafts. - determine whether turbulent flow or increased wall shear stress is present in patients with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43202

Source
ToetsingOnline

Brief title
4D-flow MRI after VSRR, mechanical AVR or septal myectomy

Condition

- Cardiac valve disorders

Synonym
prosthetic heart valve, valve sparing aortic replacement

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Foundation (Appelvink fonds)

Intervention

Keyword: 4D flow, Aorta, Aortic valve, MRI

Outcome measures

Primary outcome

blood flow velocity and patterns, flow turbulence, wall shear stress and energy

loss

Secondary outcome

not applicable

Study description

Background summary

Valve sparing aortic root replacement is a cardiac surgery procedure used to treat aneurysms of the aortic root without replacing the aortic valve. Two valve-sparing procedures are currently being performed in modern surgical practice: the David *reimplantation* technique and the Yacoub *remodeling* procedure. Many studies have been conducted comparing these treatment modalities and have found that early and late mortality, cardiopulmonary bypass time and aortic cross clamp times were comparable. Several studies have reported that postoperative freedom from aortic insufficiency was more frequent after the David procedure than the Yacoub procedure, raising the question as to whether technique-specific differences in blood flow are associated with postoperative aortic valve function.

Aortic valve stenosis is the most common form of valvular heart disease and is often a progressive disease. Surgical aortic valve replacement (AVR) is the only definitive treatment for severe stenosis and can be performed by replacing the calcified aortic valve with either a mechanical valve or a bioprosthetic tissue valve. Mechanical valves are made of pyrolytic carbon and are designed to last a lifetime. However, it is possible that their bicuspid design induces changes in wall stress and blood flow patterns in the aortic root. It is

believed that turbulent flow across aortic valve prostheses could lead to increased wall shear stress, influencing aortic wall degradation and resulting in aortic root dilatation.

Hypertrophic cardiomyopathy (HCM) is a heterogeneous disease of the myocardium and is characterized by increased left ventricular wall thickness. Left ventricular outflow tract (LVOT) obstruction occurs in up to 70% of patients and can be life-threatening. The most commonly performed surgical procedure in patients with HCM is septal myectomy, a procedure in which a part of the myocardial septum is excised, resulting in relieve of the LVOT obstruction and restoration of blood flow through the aorta. However, very little is known about the effect of this intervention on the blood flow patterns through the aortic valve and into the aortic root and ascending aorta.

Recently, 4D flow magnetic resonance imaging (MRI) has become available to assess flow patterns and hemodynamic parameters across heart valves in multiple dimensions over time. This allows for an objective analysis of blood flow and other hemodynamic parameters in these patients.

Study objective

- investigate blood flow patterns and energy loss due to viscous dissipation or turbulent kinetic flow in the aorta in patients with aortic root grafts.
- determine whether turbulent flow or increased wall shear stress is present in patients with mechanical aortic valve prostheses
- investigate blood flow patterns and energy loss due to viscous dissipation or turbulent kinetic flow in the aorta in patients after septum myectomy.

Study design

Cross-sectional retrospective pilot study

Study burden and risks

No risks
Total scantime is approximately 40 minutes, if possible planned during regular visit in outpatient clinic

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients who had a valve sparing aortic root replacement by a David or Yacoub procedure, a mechanical aortic valve implantation or a septal myectomy due to hypertrophic cardiomyopathy

Exclusion criteria

Contra-indications for MRI(see protocol for specification)
Cardiac surgery less than six months ago

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:	Recruitment stopped
Start date (anticipated):	03-02-2017
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	16-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL57372.018.16

Study results

Date completed:	01-01-2020
Actual enrolment:	44

Summary results
Trial ended prematurely