Hemodynamic characterization in hypertrophic cardiomyopathy after septal myectomy +/- mitral valve repair: a 4D-flow MRI study

Published: 05-05-2022
Last updated: 05-04-2024

Although this procedure has been performed for more than 20 years and clinical results after myectomy combined with AMVLE are satisfactory, very little is known about the effect of surgical myectomy intervention on the blood flow through the aortic...

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

Summary

ID

NL-OMON50330

Source
ToetsingOnline

Brief title
4D-flow hemodynamics after septal myectomy in HCM

Condition

- Myocardial disorders

Synonym
Hypertrophic cardiomyopathy

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 4D flow MRI, Hypertrophic cardiomyopathy, Mitral valve repair, Myectomy

Outcome measures

Primary outcome

The main study parameters are;

- blood flow velocity

- wall shear stress and energy loss over the aortic valve, the ascending

aorta, the aortic arch and descending aorta

Secondary outcome

Routine MRI parameters;

- enddiastolic and endsystolic volumes

- stroke volume

- ejection fraction

Study description

Background summary

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 is often caused by systolic anterior motion (SAM) of the mitral valve, a paradoxical phenomenon in which the anterior mitral valve leaflet (AMVL) is pulled towards the LVOT during systole.

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, combined with mitral valve repair which consists of anterior mitral valve leaflet extension (AMVLE) to stiffen the midsegment of the AMVL.

Study objective

Although this procedure has been performed for more than 20 years and clinical results after myectomy combined with AMVLE are satisfactory, very little is known about the effect of surgical myectomy intervention on the blood flow through the aortic valve and into the aortic root and ascending aorta. Therefore, the aim of this study is to investigate blood flow patterns and wall shear stress in patients after surgical septal myectomy +/- mitral valve repair.

Study design

Single center pilot study.

Study burden and risks

Since all the elements of this study are harmless and carry no risk, the overall risk is considered minimal.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients that underwent septal myectomy +/- mitral valve repair due to hypertrophic cardiomyopathy

Exclusion criteria

- Have underwent a cardiac reoperation after the initial surgical myectomy +/- MVR procedure
- Have major comorbidity besides HCM
- Are under the age of 18.
- Have claustrophobia or another contra-indication for MRI.
- Are not able to provide written informed consent.

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):	05-11-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-05-2022
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	NL79654.018.21