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Changes in aortic blood flow over several years in patients with diseases of the aortic valve measured by cardiac MRI

Submission date
04/07/2018

Recruitment status
No longer recruiting

Registration date
07/08/2018

Overall study status
Completed

Last Edited
21/09/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
4D flow is a newly developed MRI scanner that allows blood flow to be visualized and quantified. This means that blood flow pattern, volumes, velocity (aortic hemodynamics) can be examined, along with wall shear stress, which shows whether the aorta is affected by cardiac disease. Aortic stenosis, where the opening of the aortic valve is constricted, and bicuspid valves, are both forms of aortic valve disease. This can lead to altered blood flow patterns and increased wall shear stress. This study aims to investigate the changes in aortic blood flow and wall shear stress over time in patients with aortic valve diseases.

Who can participate?
Patients over 18 years of age with either a tricuspid aortic valve with stenosis or a bicuspid aortic valve.

What does the study involve?
Each patient receives two cardiovascular MRI examinations. The first is after inclusion in the study and the second is 4-7 years later.

What are the possible benefits and risks of participating?
A benefit to patients is a thorough, high-level examination of the heart. Clinically relevant information on the disease can be made available to the participant upon request and the participant will be made aware of any incidental pathological findings.
The possible risk to patients is the use of a magnetic field to collect the images, which means that any metallic (magnetic) objects, along with objects within the body (such as implants) are of risk. Additionally, there is a small risk of temporary dizziness and light flashes whilst leaving the MRI scanner.

Where is the study run from?
Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center a joint cooperation between the Charité University Medicine Berlin and the Max Delbrueck Center for Molecular Medicine, and HELIOS Klinikum Berlin Buch, Department of

Cardiology and Nephrology
Lindenberger Weg 80
Berlin
Germany
13125

When is the study starting and how long is it expected to run for?
The study started in November 2009 and will run until May 2018.

Who is funding the study?
Working Group Kardiale MRT of the Charité University Medicine Berlin.

Who is the main contact?
Professor Jeanette Schulz-Menger
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
4D FU (internal study code)

Study information

Scientific Title
Longitudinal evaluation of aortic hemodynamics in patients with aortic stenosis and patients with bicuspid aortic valve using 4D flow in cardiovascular magnetic resonance imaging - A follow up investigation

Study objectives

4D flow MRI can show changes of aortic flow patterns and additional hemodynamic parameters such as wall shear stress in patients with aortic valve pathologies over time. The pattern of aortic blood flow turbulences, and extent and degree of the wall shear stress can predict development or progress of changes in the ascending aorta.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charité University of Berlin, 27/07/2011, EA1/183/11

Study design
Observational longitudinal single-center study over the time of up to 7 years

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Patients with tricuspid aortic valve or bicuspid aortic valve, with or without stenosis.

Interventions
Two cardiac magnetic resonance examinations were performed per patient to acquire images displaying the aortic flow. Each patient received one examination after inclusion in the study and one 4 to 7 years later. The examination took approximately 1 hour and was performed using 3 Tesla Siemens Verio Scanner and was without application of contrast agent or any other drug. A physician specialising in cardiac MRI was present during the whole time of the examination.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Images of the aorta and aortic flow were acquired using 4D flow MRI at the beginning of the study and 4-7 years following this. These images were analysed for the following and the results from each time point compared:
1. Flow patterns
2. Volumes
3. Wall shear stress

Key secondary outcome(s))
N/A

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Written consent
3. Known aortic stenosis and/or bicuspid aortic valve

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Claustrophobia
2. Contraindications to CMR, including implants or metallic objects
3. Pregnant

Date of first enrolment
27/07/2011

Date of final enrolment
01/05/2018

Locations

Countries of recruitment
Germany

Study participating centre
Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center a joint cooperation between the Charité University Medicine Berlin and the Max-Delbrueck Center for Molecular Medicine, and HELIOS Klinikum Berlin Buch, Department of Cardiology and Nephrology, Berlin, Germany
Lindenberger Weg 80
Berlin
Germany
13125

Sponsor information

Organisation
Charité University Medicine Berlin

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Not defined

Funder Name
Charité University Medicine Berlin - Working Group Kardiale MRT

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to reasons of data protection laws in Germany. However, upon request methodology and data set structure can be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/02/2023	21/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes