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Analysis of blood flow in the aorta and heart structure in heart and blood vessels diseases using magnetic resonance imaging

Submission date 13/04/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/05/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/05/2024	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
In patients with heart and blood vessel diseases, changes occur in the way blood flows through the aorta (the main artery) and the structure of the heart. These changes are important because they affect the overall function of the heart and the delivery of oxygenated blood to the body. When people have heart and blood vessel diseases, the aorta may have blockages or blood clots, which can reduce blood flow. This means that organs and tissues may not receive enough oxygen and nutrients. Additionally, the structure of the heart can become abnormal, leading to problems with pumping blood effectively. These issues contribute to the progression of cardiovascular diseases.
A 7T MRI (Magnetic Resonance Imaging) machine is a powerful medical imaging device that uses a strong magnetic field to create detailed pictures of the inside of the body. It provides higher resolution and more accurate images compared to lower strength MRI machines, aiding in better diagnosis and treatment planning.
The study aims to assess blood flow in the aorta and heart structure in patients with heart and blood vessel diseases using 7T MRI.

Who can participate?
Adult patients with heart diseases: aortic valve pathologies, hypertrophic heart disease with obstruction and patients with hypertension.

What does the study involve?
7T MRI scan of the heart and aorta for 60 minutes.

What are the possible benefits and risks of participating?
Benefits: New insight into diseases and interaction of the pathology with heart function and tissue can be obtained in higher resolution and reduction of the measuring time
Risks: Dizziness, hot or cold feeling, seeing flashes, muscle contractions, nausea.

Where is the study run from?
Charité - Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
January 2018 to May 2024

Who is funding the study?
Charité - Universitätsmedizin Berlin (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CIV-18-01-022805

Study information

Scientific Title
Assessment of the interaction between myocardial structure and hemodynamics in the ascending aorta in cardiovascular diseases with alteration of the outflow tract and the aortic valve using ultra-high-field magnetic resonance imaging

Study objectives
Non-invasive analysis of hemodynamics in the ascending aorta and left ventricular outflow tract (LVOT) in cardiovascular diseases using 7T MRI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2018, Landesamt fuer Gesundheit und Soziales Ethik Kommission des Landes Berlin (Fehrberliner Platz 1, 10707 Berlin, Germany; +49 30902291226; Elen.eisenstadt@lageso.berline.de), ref: CIV-18-01-022805

Primary study design
Observational

Study design
Monocentric observational cross-sectional cohort study non-randomized open study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cardiovascular diseases: aortic valve pathologies (aortic stenosis/insufficiency), hypertrophic cardiomyopathy, muscle dystrophy, heart failure with preserved ejection fraction (HFpEF), hypertension, inflammation, connective tissue disease

Interventions
Observational study: ultra-high-field magnetic resonance imaging 7T. The hemodynamics in the aorta as well as in the LVOT can be measured using 4D flow MRI. In addition, cardiovascular MRI (CMR) in 7T also allows the detection of microstructural changes due to the increased temporal resolution.

Intervention Type
Other

Primary outcome(s)
Evaluation of the hemodynamics in the left ventricular outflow tract area using 4D MRI on the 7T MRI:
1. Flow Volumes (forward and reverse flow in ml)
2. Wall shear forces in N/m²
3. Blood flow velocities in m/s

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/05/2024

Eligibility

Key inclusion criteria
Healthy volunteers:
1. Aged at least 18 years

Patients
1. Presence of one of the following pathologies: aortic valve pathology, hypertension, hypertrophic cardiomyopathy with narrowing of the LVOT
2. Informed consent
3. Legal capacity
4. Aged at least 18 years

Participant type(s)

Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Claustrophobia
2. Any implants (e.g. pacemaker, ICD, clips, joint prostheses, >1 coronary stent)
3. Age under 18 years
4. Pregnancy, lactation
5. Rejection by patients
6. Large tattoos on the upper body (relative contraindication; individual decision together with the participant)
7. Not capable of consent
8. Placement in an institution by official or court order
9. Dependence on the investigator, trial site or sponsor

Date of first enrolment
01/05/2019

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor information

Organisation
Charité - University Medicine Berlin

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité – Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Core data can be requested upon reasonable request from the principal investigator.
The datasets generated during and/or analysed during the current study are not expected to be made available due to German data protection laws.

IPD sharing plan summary
Not expected to be made available