

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/05/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Univ.-Prof. Dr. med. Jeanette Schulz-Menger
jeanette.schulz-menger@charite.de

Contact information

Type(s)
Scientific

Contact name
Dr Elias Daud

Contact details
Lindenberger Weg 80
Berlin
Germany
13125
+49 (0)30 450 540611
elias.daud@charite.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

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

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

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 measure

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/m^2
3. Blood flow velocities in m/s

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

24/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

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

Univ.-Prof. Dr. med Jeanette Schulz-Menger Leiterin der AG „Kardiale MRT“ Charité

Universitätsmedizin Berlin

Lindenberger Weg 80

Berlin

Germany

13125

Sponsor information

Organisation

Charité - University Medicine Berlin

Sponsor details

Chariteplatz 1

Berlin

Germany

10117

+49 (0)30 450 50

jeanette.schulz-menger@charite.de

Sponsor type

Hospital/treatment centre

Website

<https://www.charite.de/en/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2026

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