# 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	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date	gistration date Overall study status	Statistical analysis plan
31/05/2023	Completed	Results
Last Edited	Condition category Circulatory System	Individual participant data
13/05/2024		[] 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.-Pro.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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

## Study design

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

## Primary study design

Observational

## 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
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

#### 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes