# Changes in cardiovascular magnetic resonance images by using magnetic resonance imaging scanner at different sites

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/11/2020		☐ Protocol		
Registration date 30/12/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 21/10/2025	Condition category Circulatory System	[] Individual participant data		

# Plain English summary of protocol

Background and study aims

The techniques for cardiac magnetic resonance imaging (MRI) are established worldwide and the quantification of heart function (in pumping blood around the body) and the volume of the chambers of the heart. MRI is now part of routine clinical examinations. Nevertheless, there are still location-related differences in the way these images are captured and in analysing the results.

Furthermore, in addition to the established measurements for determining the function of the heart muscle, there have recently been new approaches to characterizing the heart muscle and for seeing and calculating the dynamics of blood flow.

In order to perform larger studies that involve multiple different sites, there is a need to standardize MRI techniques and to establish new innovative techniques. This will also enable patients in a clinical setting to change their diagnostic center without the risk of loss or misinterpretation of results.

#### Who can participate?

Adult healthy volunteers, and adult patients with hemodynamic pathologies (such as aortic stenosis, hypertrophic cardiomyopathy, hypertensive heart disease, aortic insufficiency, and connective tissue disease of the aorta) or systemic disease (such as heart failure with preserved ejection fraction, muscular dystrophy, and inflammatory heart disease)

#### What does the study involve?

20 healthy volunteers will have an MRI scan of the heart at 5 different sites to establish and standardize the measurements for function, heart muscle composition, and blood flow dynamics. The images for each individual between the 5 sites will be used to identify differences in imaging and to identify factors influencing the capture and evaluation of these images. By identifying potential factors, these differences may then be reduced. In the case where influencing factors cannot be avoided, algorithms will be created so that a comparison of the measurements of the different MRI devices will be standardised across all 5 locations.

800 patients with certain heart diseases who have undergone an MRI scan at a single site will have their images analysed. For these patients abnormalities of the measurements are expected as a result of their illness. As these diseases are not common, a sufficient number of patients can only be recruited through multicenter studies. The precision and accuracy of the MRI measurements for these patients will be assessed.

What are the possible benefits and risks of participating?

All participants will get a functional analysis of their heart. As the access to cardiac MRI is still limited, this provides additional information for the participants. The risks are relatively low, as there are only a few side effects known (such as dizziness) that can occur during a cardiac MRI scan when complying with the inclusion and exclusion criteria. In case of adverse events such as dizziness during the scan, the scan can be interrupted at any time or at the volunteer's request. After leaving the scanner, the dizziness usually fades without needing any further intervention. No contrast agent or other drug is administered during the study.

#### Where is the study run from?

Working Group on Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center (ECRC) cooperation between the Charité University Medicine Berlin (Germany) and the Max-Delbrueck Center for Molecular Medicine (Germany), and HELIOS Klinikum Berlin Buch (Germany)

When is the study starting and how long is it expected to run for? From January 2019 to July 2024

Who is funding the study? German Centre for Cardiovascular Research (DZHK) (Germany)

Who is the main contact? Prof Jeanette Schulz-Menger stephanie.wiesemann@charite.de

# **Contact information**

# Type(s)

Scientific

#### Contact name

Prof Jeanette Schulz-Menger

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

DZHK study (internal study code)

# Study information

#### Scientific Title

Evaluation of the precision and accuracy of quantifications of cardiovascular magnetic resonance imaging exams

#### **Study objectives**

There is no difference in quantitative parameters of cardiovascular magnetic resonance imaging at magnetic resonance imaging scanner at different sites in healthy volunteers and patients with certain pathologies.

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 05/09/2019, the ethical board of Charité – Berlin University of Medicine (Campus Mitte, Charitéplatz 1, 10117 Berlin, Germany; +49 30 450 517222; ethikkommission@charite.de), ref: EA1/183/19

## Study design

Multi-centre observational cohort study

# Primary study design

Observational

# Study type(s)

Diagnostic

# Health condition(s) or problem(s) studied

Cardiac disease, aortic stenosis, hypertrophic cardiomyopathy, hypertensive heart disease, aortic insufficiency, connective tissue disease of the aorta, heart failure with preserved ejection fraction, muscular dystrophy, inflammatory heart disease

#### Interventions

Healthy volunteers will have 5 cardiac MRI exams (at each different centre) and patients will each have 1 cardiac MRI exam. The study will use different imaging techniques for measurements of function, volumes, mass, and hemodynamics (forward, backward flow, regurgitation fraction, and wall shear stress) of the heart and myocardial tissue differentiation

(T1-weighted, T2-weighted, T2\*-weighted times, fat-water- measurements, spectroscopy). All scanners are 3 Tesla scanners by Siemens (Siemens Healthineers, Erlangen, Germany).

#### Intervention Type

Procedure/Surgery

#### Primary outcome(s)

1. Quantitatively detectable cardiovascular MRI measurement methods of function, volumes, mass, hemodynamics (forward, backward flow, regurgitation fraction, wall shear stress) and myocardial differentiation (T1, T2, T2 \* times, fat-water- measurements, spectroscopy) on the MRI scanner of the different sites measured through analysis of MRI scans taken at baseline

#### Key secondary outcome(s))

- 1. Quantitatively detectable cardiovascular MRI measurement methods of the function volumes, mass, hemodynamics (forward, reverse flow, regurgitation fraction, wall shear stress) and myocardial differentiation (T1, T2, T2 \* times, fat-water images, spectroscopy) for MRI investigations carried out twice in a row at the same location measured through analysis of MRI scans taken at baseline
- 2. Image quality measured as a semiquantitative score, as well as a calculation of contrast-to-noise and signal-to-noise ratio of the measurements on the MRI scanner at the different sites measured through analysis of MRI scans taken at baseline
- 3. Duration (min) of acquisition on the MRI scanner at the different sites measured through analysis of MRI scans taken at baseline

## Completion date

31/07/2024

# Eligibility

#### Key inclusion criteria

- 1. Aged >18 years
- 2. Written consent
- 3. Healthy volunteers, patients with hemodynamic pathologies (aortic stenosis, hypertrophic cardiomyopathy, hypertensive heart disease, aortic insufficiency, and connective tissue disease of the aorta), or systemic disease (heart failure with preserved ejection fraction, muscular dystrophy, and inflammatory heart disease)

# Participant type(s)

Healthy volunteer, Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

### Lower age limit

18 years

Sex

#### Key exclusion criteria

- 1. Healthy volunteers with any known cardiac disease
- 2. Contraindication to cardiovascular magnetic resonance

#### Date of first enrolment

01/08/2020

#### Date of final enrolment

01/06/2023

# Locations

#### Countries of recruitment

Germany

# Study participating centre Charité Campus Benjamin Franklin

Neurology Department Lindenberger Weg 80 Berlin Germany 13125

# Study participating centre Charité Campus Mitte

Neuroscience Department Charitépl. 1, Berlin Germany 10117

## Study participating centre Charité Campus Virchow Klinikum

Augustenburger Pl. 1 Berlin Germany 13353

# Study participating centre

Cardiovascular Magnetic Resonance, Experimental and Clinical Research Center (ECRC)

Charitépl. 1

Berlin Germany 10117

Study participating centre HELIOS Klinikum Berlin Buch

Department of Cardiology and Nephrology Schwanebecker Chaussee 50 Berlin Germany 13125

# Sponsor information

# Organisation

Charité

#### **ROR**

https://ror.org/001w7jn25

# Funder(s)

# Funder type

Research organisation

#### **Funder Name**

Deutsches Zentrum für Herz-Kreislaufforschung

# Alternative Name(s)

German Centre for Cardiovascular Research, DZHK Germany, Zentrum HerzKreislaufForschung, Deutsches Zentrum für Herz-Kreislauf-Forschung e.V., Deutsches Zentrum für Herz-Kreislaufforschung e.V., DZHK, DZHK e.V.

## **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Research institutes and centers

#### Location

Germany

# **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 German data law regulations.

# 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		17/10 /2025	21/10 /2025	Yes	No
Interim results article	Results of parametric T1 and T2 mapping in healthy volunteers	14/08 /2023	14/08 /2023	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes