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

Submission date 16/11/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/12/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/08/2023	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2019

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)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 healthy volunteers and 800 patients (25 patients per pathology per site): 500 patients with hemodynamic pathologies; 300 patients with systemic disease

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,
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Study participating centre
Charité Campus Virchow Klinikum
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Sponsor type
University/education

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ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Research organisation

Funder Name
Deutsches Zentrum für Herz-Kreislaufforschung

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

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Germany

Results and Publications

Publication and dissemination plan
We intend to publish the results in a high-impacted peer-reviewed journal.

Intention to publish date
31/07/2024

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

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Interim results article	Results of parametric T1 and T2 mapping in healthy volunteers	14/08/2023	14/08/2023	Yes	No