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Precise evaluation of myocardial damage by cardiac MRI – QUIEROMR

Submission date 26/10/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/12/2020	**Overall study status** Completed	
Last Edited 15/01/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Nearly 20 years ago researchers proved that it is possible to detect subtle changes in the myocardium (heart muscle) using cardiac MRI (CMR). Many disorders affecting the heart lead to a replacement of normal cells by fibrous tissue. Using CMR this process can be seen by applying a contrast agent to detect so-called late gadolinium enhancement (LGE). This method is considered to be the reference method for the detection of myocardial scars. This method has two major drawbacks: it is highly operator dependent and subjective, on patients with reduced kidney function are often excluded from contrast-based scans. To tackle these obstacles parametric techniques have been developed to assess myocardial damage with quantitative markers (e.g. T1 and T2 values). Previous studies could show that these tissue markers have diagnostic, therapeutic and prognostic implications. At the moment a separate scan has to be performed for each marker, taking more time and making a complete coverage of the ventricle impossible. The aim of this study is to assess new parametric techniques that acquire more than one parameter at a time in various heart diseases. The researchers expect to precisely detect myocardial damage in a shorter time. The study is organized under the HORIZON2020 Project QUIERO (Quantitative Imaging Enables Reproducible Outcomes) EU Grant Nr. 18HLT05.

Who can participate?
Patients aged at least 18 with one of the following heart diseases: ischemic heart disease (acute, subacute and chronic stages), rheumatological disorders with cardiac involvement, aortic stenosis, hypertrophic cardiomyopathy. Healthy volunteers aged at least 18 without any heart, kidney, lung or systemic disorders

What does the study involve?
All patients receive one MRI scan. Patients will be scanned before and after contrast agent application similar to a routine CMR scan. Healthy volunteers will be scanned without the use of contrast agent. Participants also provide blood samples and an ECG is recorded before the MRI scan.

What are the benefits and risk of participating?
Healthy volunteers and patients will receive a short description of their heart function with or without the description of myocardial scars.

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

When is the study starting and how long is it expected to run for?
February 2020 to May 2022

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

Who is the main contact?
Prof. Jeanette Schulz-Menger
jeanette.schulz-menger@charite.de

Study website
https://quiero-project.eu/

Contact information

Type(s)
Scientific

Contact name
Mr Jan Wolfgang Groeschel

Contact details
Charité Universitätsmedizin Berlin
Campus Berlin Buch – ECRC
AG Kardiale MRT - Prof. Schulz-Menger
Lindenbergweg 80
Berlin
Germany
13125
+ 49 (0)30 450540611
jan.groeschel@charite.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Quantitative analysis of myocardial damage in patients with focal and diffuse fibrosis by applying novel parametric mapping techniques in cardiac magnetic resonance

Acronym
QUIEROMR

Study objectives
1. Multi-parametric sequences allow the precise quantification of myocardial damage. There is no clinically relevant difference regarding the detection of focal and diffuse fibrosis by native T1 values obtained by multi-parametric sequences in comparison to reference methods.
2. Multi-parametric sequences allow the precise quantification of myocardial edema. There is no clinically relevant difference regarding the detection of myocardial edema by T2 values obtained by multi-parametric sequences in comparison to reference methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2020, ethics committee of Charité University Medicine Berlin Campus Mitte (Charité Medical Faculty, Charité – Universitätsmedizin Berlin, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; +49 (0)30 450 517 222; ethikkommission@charite.de), ref: EA4/166/20

Study design
Observational single-center cohort study

Primary study design
Observational

Secondary study design
Case-control 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
Diffuse and focal fibrosis in patients with cardiovascular disorders

Interventions

Patients are scanned once to assess possible focal or diffuse fibrosis using quantitative imaging techniques in cardiac MRI. Blood analysis is carried out before the MRI scan to measure NTproBnP, high-sensitive Troponin T, hematocrit, glomerular filtration rate. Physical exam of the cardiovascular apparatus and an ECG are carried out before the MRI scan as well.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Myocardial T1 and T2 times, measured using novel and reference parametric mapping techniques once during the CMR scan (single timepoint)

Secondary outcome measures
1. Detection and size of myocardial fibrosis using late gadolinium enhancement techniques and extracellular volume (ECV) by applying CMR once (single timepoint)
2. Time for each acquisition and per slice measured using the DICOM tags after images are obtained

Overall study start date
03/02/2020

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. Signed consent
2. Age at least 18 years (no upper limit)
3. For patients: previously detected pathology on MRI including: ischemic heart disease (acute, subacute and chronic stages), rheumatological disorders with cardiac manifestations, aortic stenosis, hypertrophic cardiomyopathy
4. For healthy volunteers: absence of cardiac, pulmonary, renal or systemic disorders

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 healthy volunteers, 30 patients with ischemic heart disease in varying stages, 30 patients with non-ischemic heart disease (including rheumatological disorders with cardiac manifestations, aortic stenosis, hypertrophic cardiomyopathy)

Key exclusion criteria
1. Any contraindication for MRI
2. Chronic renal failure (glomerular filtration rate <30ml/min)
3. Previous participation in this study
4. Known allergy against MRI contrast agent
5. Pregnancy

Date of first enrolment
01/01/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Germany

Study participating centre
Charité University Medicine Berlin
Lindenberger Weg 80
Berlin
Germany
13125

Study participating centre
Max-Delbrueck Center for Molecular Medicine
Robert-Rössle-Straße 10
Berlin
Germany
13125

Study participating centre
HELIOS Klinikum Berlin Buch
Department of Cardiology and Nephrology
Berlin
Germany
13125

Sponsor information

Organisation
Charité

Sponsor details
Working Group Kardiale MRT
Lindenberger Weg 80
Berlin
Germany
13125
+49 (0)30 940152903
jeanette.schulz-menger@charite.de

Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/en/charite/

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. There will be no additional documents available.

Intention to publish date
31/05/2022

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 data protection laws in Germany. However, upon request the methodology and dataset structure can be shared.

IPD sharing plan summary
Not expected to be made available