

# Precise evaluation of myocardial damage by cardiac MRI – QUIEROMR

<b>Submission date</b> 26/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/01/2021	<b>Condition category</b> 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

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

## 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  
Lindenberweg 80  
Berlin  
Germany  
13125  
+ 49 (0)30 450540611  
jan.groeschel@charite.de

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## Study type(s)

Diagnostic

## 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(s)

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

## Key secondary outcome(s)

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

**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**

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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes