

# The evaluation of heart muscle changes in muscular dystrophies applying cardiac magnetic resonance: follow-up study

<b>Submission date</b> 26/08/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/11/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Facioscapulohumeral muscular dystrophy (FSHD) and Myotonic dystrophy Type 2 (PROMM) are a genetic disease that causes weakness in the skeletal muscles. Patients may suffer from heart problems like dangerous heart rhythm disturbances, shortness of breath also sudden death have been reported. It is suspected that an unknown injury of the heart can be a reason. Over the last couple of year's cardiac magnetic resonance imaging (MRI) (a type of scan that uses strong magnetic fields and radio waves to create an image of the heart) has become the best method for looking at scars and other changes in the heart muscle (fat, inflammation). The aim of this study is to identify heart muscle changes within of 2-4 years in patients with DM1/FSHD and its relation to heart rhythm disturbances.

### Who can participate?

Participants who have a FSHD Type 1 and PROMM

### What does the study involve?

All participants get a detailed work-up by a cardiologist (heart doctor) including a cardiac MRI due to muscle dystrophy. The participant receives a cardiac MRI protocol and innovative techniques. This prolongs the MRI scan by only approximately ten minutes. There are no additional applications of contrast-media or medication.

### What are the possible benefits and risks of participating?

Participants may benefit from the detection of early myocardial changes applying MRI may help to stratify further therapy and has a potential impact on prognosis and heart muscle remodeling. The clinical results will also be available for each patient. There are no direct risks with participating.

### Where is the study run from?

This study is a work group Cardiovascular Magnetic Resonance, Experimental and Clinical

Research Center, a joint cooperation between the Charité University Medicine Berlin (Germany) and the Max-Delbrueck Center for Molecular Medicine (Germany), and HELIOS Klinikum Berlin Buch, Department of Cardiology and Nephrology, Berlin (Germany).

When is the study starting and how long is it expected to run for?  
November 2016 to January 2019

Who is funding the study?  
Charité University Medicine Berlin (Germany)

Who is the main contact?  
Professor Jeanette Schulz-Menger

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jeanette Schulz-Menger

**ORCID ID**  
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**Contact details**  
Charité University Medicine Berlin Campus Buch  
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Berlin  
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13125

## Additional identifiers

**Protocol serial number**  
MD-CMR- Follow-up

## Study information

**Scientific Title**  
Cardiac involvement in muscular dystrophies assessment by cardiovascular magnetic resonance: follow up study

**Study objectives**  
The aim of this prospective diagnostic follow up trial is to evaluate the efficacy of a comprehensive cardiovascular magnetic resonance (CMR) protocol to predict myocardial tissue injury and heart rhythm abnormalities in facioscapulohumeral muscular dystrophy type 1 (FSHD1) patients and myotonic dystrophy Type 2 (DM2, PROMM) patients.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Charité University Medicine Berlin Campus Mitte, 10/04/2017, ref: EA1/042/17

**Study design**

Prospective diagnostic follow-up trial

**Primary study design**

Observational

**Study type(s)**

Diagnostic

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

Patients with a genetically confirmed diagnosis FSHD Type 1 and PROMM who took part in a previous studies

**Interventions**

Participants receive a detailed work up (including an ECG, Holter and Echocardiogram) by a cardiologist. The participants undergo a CMR. They receive the same CMR protocol as during the previous study.

CMR is applied at a 1.5 T Scanner (MAGNETOM AvantoFit®, Siemens Healthcare, Erlangen, Germany) using a 32 channel surface coil. Cine imaging is performed applying state of the art steady state precession sequences to determine the global cardiac performance. For myocardial tissue differentiation, parametric T1 and T2 mapping, fat/water separated imaging and focal fibrosis imaging (Late Gadolinium Enhancement, LGE) are performed.

There are no additional treatments.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Increase of myocardial tissue injuries is measured using magnetic resonance imaging visually looking for presence and extent of lesions like fat and scar as well as diffuse myocardial changes at yearly follow up.

**Key secondary outcome(s))**

Heart rhythm disturbances is measured using ECG and ECG monitoring at yearly follow up

**Completion date**

01/01/2019

**Eligibility****Key inclusion criteria**

FSHD and PROMM patients who took part in the previous study PROMM 2013, FSHD 2015/2016

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

83

**Key exclusion criteria**

1. Known vascular, cardiac diseases (e.g. coronary artery disease, significant valvular disease, myocarditis)
2. Malign diseases or known contraindications for CMR
3. Gadolinium-based contrast-media

**Date of first enrolment**

10/04/2017

**Date of final enrolment**

01/08/2018

## **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

## Sponsor information

**Organisation**  
Charité University Medicine Berlin

**ROR**  
<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**  
University/education

**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 reasons of data protection laws in Germany. However, upon request 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="#">Results article</a>		08/11/2021	10/11/2021	Yes	No
<a href="#">Protocol article</a>	protocol	01/07/2016		Yes	No