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

Submission date
26/08/2017

Recruitment status
No longer recruiting

Registration date
29/11/2017

Overall study status
Completed

Last Edited
10/11/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal 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
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 measure
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.

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

Overall study start date
01/11/2016

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

Age group
Adult

Sex
Both

Target number of participants
84

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
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Study participating centre
HELIOS Klinikum Berlin Buch
Department of Cardiology and Nephrology
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Sponsor information

Organisation
Charité University Medicine Berlin

Sponsor details
Working Group Kardiale
MRT Lindenberger Weg 80
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13125

Sponsor type
University/education

Website
http://www.cmr-berlin.org

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

Publication and dissemination plan
Results of this study shall be published in a high-ranking peer-reviewed journal.

Intention to publish date
31/12/2018

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?
Protocol article	protocol	01/07/2016		Yes	No
Results article		08/11/2021	10/11/2021	Yes	No