ISRCTN48802295 https://doi.org/10.1186/ISRCTN48802295

Comparison of different techniques regarding visualization of scars in the heart muscle using cardiac MRI

Submission date
06/06/2017

Recruitment status
No longer recruiting

Registration date
10/07/2017

Overall study status
Completed

Last Edited
15/03/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A cardiac MRI scan is a non-invasive test where magnetic and radio waves are used to create pictures of the inside of the heart. Over the last couple of years cardiac MRI has become the gold standard method for looking at scars in the heart muscle. This scarring can be due to myocardial infarction (heart attack), thickening of the heart walls or inflammation of the heart muscle itself and is a very strong indicator of the likely course of these conditions. Cardiac MRI uses a technique called late gadolinium enhancement (LGE) to show scars. The gold standard LGE technique is a so-called segmented PSIR sequence and provides great image quality, but only in patients with a stable heart rhythm and able to hold their breath, which is required for the technique to work. Unfortunately, many patients do not meet these requirements. New so-called multi-slice LGE sequences are faster techniques than the gold standard method and also work for patients with irregular heart rhythm or shortness of breath. The aim of this study is to assess the accuracy of three of these novel multi-slice LGE sequences to detect and quantify scars in the heart muscle when compared to a gold standard PSIR sequence.

Who can participate?
Patients aged 18 and over referred for cardiac MRI after a heart attack (myocardial infarction), with thickened heart walls (hypertrophic cardiomyopathies), or due to suspected or known inflammation of the heart muscle cells

What does the study involve?
All participants undergo a standard cardiac MRI scan with the gold standard LGE PSIR sequence and also the new multi-slice sequences. This prolongs the MRI scan by about five minutes. The size of the myocardium (heart muscle) and image quality are compared between the scans.

What are the possible benefits and risks of participating?
Possible benefits include improved detection of scars in the heart muscle. If the multi-slice sequences are found to perform as well as the gold standard sequence, these faster sequences could be used in future to improve access to cardiac MRI by decreasing scan time at a high image quality and increasing patient comfort. As all patients receive the cardiac MRI even if they do not

participate and the scan itself is only prolonged by 5 minutes (of a 45 minutes total scan time), there is no additional risk or burden expected with participation in this study.

Where is the study run from?
HELIOS Clinic Berlin-Buch (Germany)

When is the study starting and how long is it expected to run for?
November 2014 to December 2016

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

Who is the main contact?
Prof. Jeanette Schulz-Menger

Contact information

Type(s)
Scientific

Contact name
Prof Jeanette Schulz-Menger

Contact details
Charité University Medicine Berlin
Campus Buch
Working Group Kardiale MRT
Lindenberger Weg 80
Berlin
Germany
13125

Additional identifiers

Protocol serial number
LGE COMPARE (internal study code)

Study information

Scientific Title
Comparison of fast multi-slice and standard segmented techniques for detection of late gadolinium enhancement in ischemic and non-ischemic cardiomyopathy - a prospective clinical trial

Study objectives
All tested fast multi-slice LGE sequences are non-inferior to the segmented PSIR gold standard method with regard to LGE size quantification (in gram) using a semi-automated threshold method.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics board at Charité University Medicine Berlin, Campus Mitte, 16/10/2014, ref: EA1/305/14

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Myocardial infarction, hypertrophic cardiomyopathy and inflammatory heart disease

Interventions
This is an observational study in which three different techniques are compared for visualization of myocardial fibrosis using late Gadolinium enhancement in patients with known or suspected cardiomyopathy.

Patients sent for clinically indicated cardiac LGE-based MRI with known or suspected LGE due to chronic infarction, inflammatory myocardial disease and hypertrophic cardiomyopathy (HCM) are prospectively recruited. The indication for the MRI itself is clinical. However, for this study the MRI protocol is extended by the tested multislice LGE sequences for approximately 5 extra minutes. LGE images are acquired using three different LGE sequences. All patients were scanned with all three LGE sequences (intraindividual comparison). All LGE sequences are then assessed as follows: image quality is evaluated with a 4-point scoring system. Contrast-to-noise ratios and acquisition time are measured. Size of LGE is quantitatively assessed using a semi-automated threshold method. All assessments are done by blinded readers.

Intervention Type
Other

Primary outcome(s)
Size of myocardium with late Gadolinium enhancement in each tested MR sequence, measured by semiautomated threshold method in MRI DICOM data at one timepoint, the date of the MRI (no follow up)

Key secondary outcome(s))
1. Contrast-to-noise ratio in each tested MR sequence, measured using MRI DICOM data
2. Image quality, scored on a 4-point-scaling system based on visual assessment by blinded readers
Measured at at one timepoint, the date of the MRI (no follow up)

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Known or suspected chronic myocardial infarction, hypertrophic cardiomyopathy or inflammatory heart disease
2. Clinical indication for MR exam with late gadolinium enhancement
3. Age range ≥18 years (no upper limit)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Any contraindication for MR exam
2. Acute or chronic renal failure with GFR <30ml/min

Date of first enrolment
01/11/2014

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Germany

Study participating centre
HELIOS Clinic Berlin-Buch
Germany
13125

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 is not expected to be made available due to reasons of data protection laws in Germany. However, upon request methodology and data set 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?
Results article	results	19/02/2018	15/03/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes