

Comparison of two different techniques to visualize narrowing of coronary arteries using cardiac MRI: the SPARSE perfusion study

Submission date 15/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/09/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Stress Perfusion imaging using magnetic resonance Imaging plays a major role in non-invasive detection of coronary artery disease (CAD). It has been established as a robust non-invasive diagnostic tool in patients with moderate probability for relevant coronary artery disease, i.e. due to chest pain or pathologic changes in the electrocardiogram. The specificity (approx. 80%) and sensitivity (approx. 90%) of adenosine stress Perfusion Imaging are comparably high when compared to other Methods such as stress echocardiography or single-Photon Emission computed tomography (SPECT), however, is limited by spatial and temporal Resolution. New Perfusion sequences utilize a different method for Image Acquisition and enable higher resolutions which might lead to further increase of sensitivity and specificity of this method. In this prospective study, we aim to compare such a novel gradient echo-based perfusion sequence (SPARSE) and a conventional gradient echo sequence (TurboFLASH) with regard to diagnostic performance. Doing this we might be able to increase diagnostic accuracy of the adenosine-perfusion MR in the future.

Who can participate?

Adult patients with suspected coronary artery disease who are scheduled for coronary angiography.

What does the study involve?

All participants receive two heart MRI scans before their scheduled coronary angiography. Both MR scans are performed in a Standard Fashion with adenosine-perfusion Imaging and in each scan one of the two tested sequences is used.

What are the possible benefits and risks of participating?

Participants might benefit from better detection of coronary artery disease using MRI. During the MRI scan, participants receive a standard dose of contrast medium that in rare occasions can cause allergic reactions. However, there are no study-associated side effects that exceed those of a regular MRI scan.

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

When is the study starting and how long is it expected to run for?
April 2015 - December 2016

Who is funding the study?
The cost of this study will be funded by the research group itself through university-affiliated research grants. No external funding is needed.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPARSE perfusion (internal study code)

Study information

Scientific Title

Comparison of compressed sensing-based gradient echo perfusion sequence and conventional gradient echo sequence in assessment of myocardial ischemia

Acronym

SPARSE

Study objectives

Compressed sensing-based gradient echo perfusion sequence SPARSE is non-inferior to conventional gradient echo sequence with regard to visual perfusion assessment by two blinded readers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 31/03/2015, Ethics board at Charité University Medicine Berlin (Ethikkommission der Charité, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin; +49-30-450517222; e-mail: ethikkommission@charite.de), ref: EA1/081/15

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

Coronary artery disease

Interventions

Participants receive two adenosine-stress myocardial MR scans (one for each tested perfusion sequence*) and a coronary angiography as reference standard within six weeks. On both MR scans, coronary perfusion is analyzed visually and by two semi-quantitative methods (upslope myocardial perfusion reserve and fermi deconvolution model) in order to compare myocardial perfusion. Coronary angiography is used as a reference Standard, where any visual stenosis > 90% or fractional flow reserve < 0.75 is considered a hemodynamically significant stenosis.

* Compressed sensing-based gradient echo perfusion sequence AND conventional gradient echo sequence

Intervention Type

Procedure/Surgery

Primary outcome measure

Detection of stenosis by visual assessment of myocardial perfusion by two blinded readers for each MR scan.

Secondary outcome measures

Semi-quantitative perfusion analysis for both MR scans using two methods: upslope myocardial perfusion reserve and fermi deconvolution model

Overall study start date

05/01/2015

Completion date

31/12/2016

Eligibility**Key inclusion criteria**

1. Planned invasive coronary angiography due to clinical suspicion of coronary artery disease
2. Age at least 18 years (no upper limit)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25

Total final enrolment

23

Key exclusion criteria

1. Any contraindication for contrast-based MRI or adenosine
2. Chronic renal failure (glomerular filtration rate < 30ml/min)
3. Previous participation in this study
4. Persistent or permanent atrial fibrillation
5. Coronary Intervention within 30 days before study inclusion
6. Myocardial infarction within 6 months before inclusion

Date of first enrolment

01/04/2015

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

Germany

Study participating centre

HELIOS Hospital Berlin-Buch

Schwanebecker Chaussee 50

Berlin

Germany

13125

Sponsor information

Organisation

Working Group Cardiac MRI @ Charité University Medicine Berlin & HELIOS Hospital Berlin-Buch

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/05hgh1g19>

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

We are intending to publish at least one research article in a high-ranking peer-reviewed journal, such as JCMR (impact factor 6.5)

Intention to publish date

30/09/2019

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 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		01/10/2020	10/09/2021	Yes	No