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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

Registration date
30/04/2019

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 deconvution 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 deconvution 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 suspection 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

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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