

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>15/03/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/04/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>10/09/2021       | <b>Condition category</b><br>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?  
Dr Fabian Muehlberg  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

### **Primary study design**

Observational

### **Study design**

Observational cohort study

### **Study type(s)**

Diagnostic

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 Years

## Sex

All

## 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

### 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

### 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 01/10/2020   | 10/09/2021 | Yes            | No              |