

# Magnetic resonance imaging in patients with chronic total occlusions of the coronary arteries

<b>Submission date</b> 31/03/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/07/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Atherosclerosis of the coronary arteries leads to coronary heart disease, a leading cause of mortality in developed countries. The narrowing of a coronary artery restricts the blood supply to the downstream heart muscle tissue. This can lead to the typical symptoms of chest pain, shortness of breath and a pumping weakness of the heart. A frequent finding in cardiac catheter exams is a chronic total occlusion of a coronary artery. The cardiac muscle tissue to be supplied can now die due to the insufficient blood supply or be in a kind of "sleep mode". If the heart muscle tissue is still alive, it would be worthwhile, according to the current state of knowledge, to reopen it. Therefore, vitality is assessed using cardiac magnetic resonance imaging (CMR). As far as possible and rational, the closed vessel would then be reopened in a cardiac catheter examination. This study aims to enhance patient selection for percutaneous coronary intervention (PCI) using CMR.

### Who can participate?

Patients of the Heart Clinic Ulm with a chronic total coronary occlusion

### What does the study involve?

The study has an observational design. Every patient is treated according to current guidelines. No additional invasive treatment or diagnostics are carried out. The success of the procedure is checked with an MRI. Quality of life and symptom severity are assessed before and repeatedly after revascularization using a questionnaire.

### What are the possible benefits and risks of participating?

There are no expected benefits or risks of participating.

### Where is the study run from?

Heart Clinic Ulm (Germany)

### When is the study starting and how long is it expected to run for?

December 2017 to April 2024

Who is funding the study?  
Heart Clinic Ulm (Germany)

Who is the main contact?  
Dr Johannes Kersten  
johannes.kersten@uni-ulm.de

## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CTO1

## Study information

**Scientific Title**  
Prognostic value of cardiac magnetic resonance in patients with chronic total coronary occlusions

**Study hypothesis**  
The aims of the current trial are:  
1. To find CMR predictive factors including cut-off values for ischemia and viability regarding symptom improvement after CTO revascularization  
2. To identify patients benefiting from CTO revascularization  
3. To assess mid-term prognosis of event-free survival and quality of life in CTO patients undergoing revascularization

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 16/04/2018, Ethics committee of the Medical Association of Baden-Württemberg (Landesärztekammer Baden-Württemberg, Ethik-Kommission, Jahnstraße 40, 70597 Stuttgart, Germany; +49 (0)711-76989-0; ethikkommission@laek-bw.de), ref: F-2018-026

### **Study design**

Single-center prospective observational 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 contact details to request a participant information sheet

### **Condition**

Chronic total coronary occlusion (CTO)

### **Interventions**

All patients with an angiographic proven CTO are screened for the study. After the CMR guided proof of viability and ischemia in the territory belonging to the CTO a first Seattle Angina Questionnaire (SAQ) for symptom severity is carried out. Then an attempt for revascularization by percutaneous coronary intervention (PCI) is done. In case of a non-successful PCI, more attempts are done when sensible. To examine the clinical benefit after successful PCI, more SAQ questionnaires were done after 3, 12, 24 and 36 months. To examine residual ischemia and a possible improvement in heart function, another CMR examination is done 3 up to 6 months after the CTO-PCI. Rates for major adverse cardiac events are recorded alongside the whole study period.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Symptom burden with angina pectoris in repeated surveys using the Seattle Angina questionnaire (SAQ) at baseline and 3, 12, 24 and 36 months

### **Secondary outcome measures**

Left and right ventricular ejection fractions, strain measurements and first-pass perfusion measured using a CMR scan at baseline and 3 up to 6 months after

**Overall study start date**

20/12/2017

**Overall study end date**

30/04/2024

## Eligibility

**Participant inclusion criteria**

All patients with angiographic proven CTO

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Participant exclusion criteria**

1. Myocardial infarctions in the last three months
2. Instable angina
3. Contraindications for CMR, gadolinium-based contrast agents or the intravenous administration of adenosine
4. Impaired renal function (glomerular filtration rate < 30ml/min)
5. Inability to give written informed consent

**Recruitment start date**

16/04/2018

**Recruitment end date**

30/04/2021

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

Heart Clinic Ulm

Magirusstr. 49

Ulm

Germany

89077

# Sponsor information

## Organisation

Heart Clinic Ulm

## Sponsor details

Magirusstr. 49

Ulm

Germany

89077

+49 (0)7319353070

peter.bernhardt@herzlinik-ulm.de

## Sponsor type

Hospital/treatment centre

## Website

<http://www.herzlinik-ulm.de/index.html>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Heart Clinic Ulm

# Results and Publications

## Publication and dissemination plan

1. Submission of the study protocol to a peer-reviewed journal in 2020
2. Interim results should be presented at the SCMR meeting in 2021
3. Publication of the final results is intended in a peer-reviewed international scientific journal in 2024

## Intention to publish date

31/12/2024

## Individual participant data (IPD) sharing plan

Participant level data are available from Dr Johannes Kersten ([johannes.kersten@uni-ulm.de](mailto:johannes.kersten@uni-ulm.de)) on reasonable request. Personal data including name and address of the participants are erased

therefore in the dataset. A clear assignment is still possible for the author via the study pseudonym.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Interim results article</a>	Baseline angina burden predicts quality of life and functional improvement in patients with viable myocardium treated for chronic total occlusion	12/07/2023	13/07/2023	Yes	No