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

Submission date 31/03/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/04/2020	**Overall study status** Completed	
Last Edited 13/07/2023	**Condition category** Circulatory System	

Plain English summary of protocol

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 bood 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
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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 objectives
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-Komission, 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

Health condition(s) or problem(s) studied
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 senseful. 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

Completion date
30/04/2024

Eligibility

Key inclusion criteria
All patients with angiographic proven CTO

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key 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

Date of first enrolment
16/04/2018

Date of final enrolment
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
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peter.bernhardt@herzklinik-ulm.de

Sponsor type
Hospital/treatment centre

Website
http://www.herzklinik-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) 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?
Interim results article	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