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

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

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 johannes.kersten@uni-ulm.de

Contact information

Type(s) Public

Contact name Dr Johannes Kersten

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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

Magirusstr. 49 Ulm Germany 89077 +49 (0)7319353070 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	Details	Date	Date	Peer	Patient-
type		create	d added	I reviewed	? facing?
<u>Interim</u> 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