ISRCTN30941346 https://doi.org/10.1186/ISRCTN30941346

Cardiac involvement in patients with inflammatory bowel disease assessed by cardiovascular magnetic resonance imaging (CMR)

Submission date
02/03/2021

Recruitment status
No longer recruiting

Registration date
16/03/2021

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with inflammatory bowel disease are at increased risk for adverse cardiovascular events, especially during active inflammatory bowel disease. Currently, there are not studies examining the underlying causes of this risk.

The study aims to assess abnormalities in the heart of patients with inflammatory bowel disease using a cardiovascular MRI scan (CMR-imaging).

Who can participate?
Patients who are 18 years or older, with a confirmed IBD diagnosis, who are able to provide informed consent, are not pregnant and are able to undergo CMR-imaging.

What does the study involve?
Participants will undergo a first CMR-imaging. Patients with signs of active inflammation will receive a second CMR scan after 5 weeks. A clinical follow-up is obtained 1 year after the first CMR scan.

What are the possible benefits and risks of participating?
In order to achieve study aims, the study team will characterise the tissue of the heart (obtained non-invasively) and therefore potentially identify patients at risk for adverse cardiovascular events. The risks of participating in this study are the usual risks associated with CMR-imaging and participants are not exposed to further risks.

Where is the study run from?
Helios Clinics Berlin Buch (Germany)

When is the study starting and how long is it expected to run for?
From April 2021 to April 2023

Who is funding the study?
Charité – Universitätsmedizin Berlin (Germany)

Who is the main contact?
Dr Maximilian Fenski, maximilian.fenski@charite.de

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
ePA 3000170

Study information

Scientific Title
Potential CArdiac MAanifestation in patients with Inflammatory bowel Disease in acute and chronic stage assessed by Cardiovascular Magnetic Resonance imaging (CAMAID-CMR)

Acronym
CAMAID-CMR

Study objectives
A significantly higher degree of diffuse or focal fibrosis, assessed by CMR, can be found in patients with inflammatory bowel disease compared to an age and sex-matched healthy control group, despite preserved LV-EF

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2020, Charité Ethics Board Berlin (Campus Charité Mitte (CCM), Chariteplatz 1, 10117 Berlin, German; +49 (0)30/450-517222; ethikkommission@charite.de), ref: EA1/198/20

Study design
Single-center observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

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
Patients with inflammatory bowel disease in acute and chronic stage

Interventions
Participants are categorized into acute or chronic stage based on IBD activity scores (Crohn's Disease Activity Index and Simple Clinical Colitis Activity Index). Each participant receives a CMR scan including LV and RV function, T1- and T2-Mapping, and fat and fibrosis assessments. Patients with signs of active inflammation will receive a second CMR scan after 5 weeks. A clinical follow-up is obtained 1 year after the first CMR scan.

Intervention Type
Other

Primary outcome measure
Diffuse or focal fibrosis measured using T1-Mapping, ECV, and late gadolinium enhancement MRI scans at baseline, 5 weeks, and 1 year

Secondary outcome measures
1. Ventricular function measured using MRI cine imaging at baseline, 5 weeks, and 1 year
2. Edema quantification using T2-Mapping MRI scans at baseline, 5 weeks, and 1 year
3. Extracellular volume quantification using T1-Mapping post-contrast agent application MRI scans at baseline, 5 weeks, and 1 year

Overall study start date

01/04/2021

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Clinically, radiologically, and histologically confirmed diagnosis of inflammatory bowel disease
3. No absolute MRI contraindications
4. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
44

Key exclusion criteria
1. Contraindications for MRI scan
2. Pregnancy
3. Known allergy to MRI contrast agent

Date of first enrolment
01/04/2021

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Germany

Study participating centre

Helios Clinics Berlin Buch
Helios Klinikum Berlin Buch
Schwanebecker Chaussee 50
Berlin
Germany
13125

Sponsor information

Organisation
Charité - University Medicine Berlin

Sponsor details
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ECRC Experimental and Clinical Research Center
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Sponsor type
Hospital/treatment centre

Website
https://www.charite.de/en/

ROR
https://ror.org/001w7jn25

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		15/09/2020	16/03/2021	No	No
Protocol file		15/09/2020	16/03/2021	No	No
Results article		05/08/2024	06/08/2024	Yes	No