

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2024	Condition category Digestive System	<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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?
Results article		05/08/2024	06/08/2024	Yes	No
Protocol file		15/09/2020	16/03/2021	No	No
Protocol file		15/09/2020	16/03/2021	No	No