

Assessing heart problems in psoriasis patients using cardiovascular magnetic resonance (CMR) imaging

Submission date 25/05/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/06/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/05/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Psoriasis is a chronic inflammatory disease with primary skin manifestation caused by a complex interaction of the immune system. It is characterized by erythematous plaques with silvery-white scales at typical predilection sites. Nail changes and joint involvement may also occur. Psoriasis is mainly treated with anti-inflammatory agents, in mild cases by local application of anti-inflammatory lotions or other creams and in moderate to severe cases by systemic treatment with immunomodulatory drugs such as biologicals.

It is already known that patients with psoriasis have an increased prevalence of cardiovascular risk factors such as metabolic syndrome, diabetes mellitus and hypertension. Patients with psoriasis are more frequently affected by severe cardiac events such as heart attacks or strokes. Consequently, cardiovascular disease significantly affects the morbidity and mortality of patients with psoriasis.

The aim of this study is the investigation of a potential myocardial involvement by cardiovascular magnetic resonance imaging (CMR) in patients with psoriasis. Subordinate to this, it will be investigated whether the severity of the disease, defined according to the therapy, correlates with the changes in the myocardium.

Who can participate?

This study includes patients diagnosed with psoriasis who also meet the following conditions:

- Age: 18 years or older
- No known severe cardiovascular disease such as coronary artery disease, myocardial infarction or condition after bypass surgery
- No pregnancy or lactation
- No general contraindications for an MRI examination (e.g. metallic implants)

What does the study involve?

All patients receive one MRI scan. In addition, a dermatologic and cardiac physical exam, a general blood test and ECG are performed.

What are the possible benefits and risks of participating?

All participants receive a cardiological check by CMR and complementary examinations, providing assessment and evaluation of cardiac function and other heart abnormalities.

Where is the study run from?

Charité Universitätsmedizin Berlin (Germany) and HELIOS Klinikum Berlin-Buch (Germany)

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

February 2021 to March 2023

Who is funding the study?

Charité Universitätsmedizin Berlin (Germany)

Who is the main contact?

Prof. Dr. Jeanette Schulz-Menger

jeanette.schulz-menger@charite.de

Contact information

Type(s)

Scientific

Contact name

Mr Leonhard Grassow

Contact details

Charité Universitätsmedizin Berlin

Campus Berlin Buch – ECRC

AG Kardiologie MRT - Prof. Schulz-Menger

Lindenberger Weg 80

Berlin

Germany

13125

+49 (0)30 450 540 615

leonhard.grassow@charite.de

Type(s)

Scientific

Contact name

Mr Jan Gröschel

Contact details

Charité Universitätsmedizin Berlin

Campus Berlin Buch – ECRC

AG Kardiologie MRT - Prof. Schulz-Menger

Lindenberger Weg 80

Berlin

Germany

13125
+49 (0)30 450 540 615
jan.groeschel@charite.de

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Deep cardiac phenotyping by cardiovascular magnetic resonance (CMR) in patients with psoriasis for the detection of potential myocardial tissue injury. PSORiasis assessment by CardiOvascular magnetic Resonance

Acronym

PSOR-COR

Study objectives

1. Patients with psoriasis but without severe previous cardiac disease show more myocardial tissue damage by late gadolinium enhancement (LGE) or parametric techniques in CMR compared to a healthy control group.
2. Higher severity of psoriasis correlates positively with detected myocardial damage. Myocardial damage includes scar/fibrosis, edema, fatty infiltration and should be detected by LGE, and parametric techniques.
3. Patients with psoriasis have larger epi- and pericardial fat mass, as measured by Fat/Water sequences on CMR, compared to a healthy control group.
4. Inflammatory markers determined by blood tests correlate positively with the potential myocardial injury.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/06/2021, Ethics Committee of Charité University Medicine Berlin Campus Mitte (Charité Medical Faculty, Charité – Universitätsmedizin Berlin, Campus Charité Mitte, Charitéplatz 1, 10117 Berlin, Germany; +49 (0)30 450 517 222; ethikkommission@charite.de), ref: EA1/130/21

Study design

Prospective observational single-center cohort study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Myocardial involvement in patients with psoriasis.

Interventions

All patients undergo cardiovascular magnetic resonance (CMR) at a 1.5 Tesla scanner with application of contrast agent to evaluate potential cardiac involvement. The images are evaluated qualitatively and quantitatively for cardiac function, dimension and mass (cine technique), signs of inflammation or diffuse fibrosis (mapping techniques), and focal fibrosis (late gadolinium enhancement). Blood tests are performed prior to the scan to determine blood count, inflammatory markers, lipids, renal function, and cardiac-specific parameters such as NTproBNP, high-sensitive troponin T. A physical examination and ECG are also performed prior to the scan.

Intervention Type

Other

Primary outcome measure

Myocardial T1 and T2 times determined by mapping techniques and detection and size of myocardial focal fibrosis by late gadolinium enhancement techniques and extracellular volume (ECV) by applying CMR once (single timepoint).

Secondary outcome measures

1. Quantitative cardiac parameters regarding function, dimension and mass of the ventricles and atria using cine-imaging techniques by applying CMR once (single timepoint).
2. Analysis of function by measuring cardiac deformation (strain) to determine longitudinal, circumferential and radial strain by applying CMR once (single timepoint).

Overall study start date

01/02/2021

Completion date

31/03/2023

Eligibility

Key inclusion criteria

1. Signed consent
2. Age ≥ 18 years (no upper limit)
3. Verified psoriasis without any of the pre-existing conditions listed under exclusion criteria

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60 patients with psoriasis, 60 healthy volunteers (healthy volunteers already included in previous studies)

Total final enrolment

64

Key exclusion criteria

1. Absolute contraindication for MRI examination
2. Severe previous cardiac disease in particular: Condition after myocardial infarction, Condition after CABG (aorto-coronary vein bypass), Coronary artery disease with or without condition after intervention (stenting)
3. Known allergy to MRI contrast agents
4. Chronic kidney disease with GFR < 30 ml/min (after CKD-EPI)
5. Pregnancy, lactation

Date of first enrolment

01/02/2022

Date of final enrolment

06/03/2023

Locations**Countries of recruitment**

Germany

Study participating centre

Charité University Medicine Berlin

Lindenberger Weg 80

Berlin

Germany
13125

Study participating centre
Max-Delbrueck-Center for Molecular Medicine
Robert-Rössle-Straße 10
Berlin
Germany
13125

Study participating centre
Helios Klinikum Berlin-Buch, Department of Cardiology and Nephrology
Schwanebecker Chaussee 50
Berlin
Germany
13125

Sponsor information

Organisation
Charité - Universitätsmedizin Berlin

Sponsor details
Campus Berlin Buch - ECRC
Working Group Kardiologie MRT
Lindenberger Weg 80
Berlin
Germany
13125
+49 (0)30 940152903
jeanette.schulz-menger@charite.de

Sponsor type
Hospital/treatment centre

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

ROR
<https://ror.org/001w7jn25>

Funder(s)

Funder type

University/education

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

01/08/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection laws in Germany. However, upon request the methodology and dataset structure can be shared.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/05/2024	21/05/2024	Yes	No