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

Submission date
25/05/2023

Recruitment status
No longer recruiting

Registration date
09/06/2023

Overall study status
Completed

Last Edited
21/05/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
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

Primary study design
Observational

Study design
Prospective observational single-center cohort study

Study type(s)
Diagnostic

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(s)
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).

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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 <30ml/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
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Study participating centre
Helios Klinikum Berlin-Buch, Department of Cardiology and Nephrology
Schwanebecker Chaussee 50
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Sponsor information

Organisation
Charité - Universitätsmedizin Berlin

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

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