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Role of heart-reactive antibodies in heart failure

Submission date 06/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/02/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 07/02/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
An acute heart failure (AHF) episode may boost an adaptive immune response against myocardial antigens that contributes to the progression of heart failure and poor prognosis. This study will address the following research questions:
1. What are the prevalence and determinants of anti-myocardial autoantibodies (pan-anti-heart, antigen-specific) and auto-reactive T cells in AHF patients?
2. What are the characteristics and determinants of the adaptive immune response to an AHF episode?
3. What is the expression of auto-antibodies over time?
4. Is the adaptive immune response following AHF associated with the progression of cardiac impairment and the prognosis of AHF patients?

Who can participate?
Patients aged 18 years and over who are hospitalized at the University Hospital Würzburg for acute heart failure

What does the study involve?
Detailed clinical, echocardiographic and immunologic assessment at the start of the study as well as 6 weeks and 6, 12, and 18 months after hospitalization.

What are the possible benefits and risks of participating?
Since this study is purely descriptive and standard medical care will not be affected, there are no study-specific risks for patients. This study will help to further strengthen the structures for collaborative HF care. By providing optimal management opportunities this structured approach will likely benefit also individual study participants.

Where is the study run from?
Dpt. Clinical Research and Epidemiology, Comprehensive Heart Failure Center Würzburg & Dpt. Medicine I, University Hospital Würzburg (Germany)

When is the study starting and how long is it expected to run for?
April 2021 to December 2026

Who is funding the study?
The study is funded by the German Research Foundation via the SFB1525, project C05

Who is the main contact?
1. Dr Caroline Morbach, morbach_c@ukw.de
2. Dr Niklas Beyersdorf, niklas.beyersdorf@uni-wuerzburg.de

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
123

Study information

Scientific Title
Acute Heart Failure Immunomonitoring Cohort Study (AHF-ImmunoCS)

Acronym
AHF-ImmunoCS

Study objectives

The overarching hypothesis is that an acute heart failure (AHF) episode boosts an adaptive immune response against myocardial antigens that contributes to the progression of heart failure and consecutively to poor prognosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/06/2021, Medizinische Ethikkommission an der Julius-Maximilians-Universität Würzburg (Josef-Schneider-Str. 4, C15, Würzburg, 97080, Germany; +49 (0)931 31 48315; ethikkommission@uni-wuerzburg.de), ref: 112/21

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

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
Acute heart failure

Interventions
Patients hospitalized for acute heart failure will be followed for 18 months. From blood drawn at baseline, 6 weeks and 6 months after decompensation, the researchers will assess the incidence of heart-reactive antibodies. They will associate these results to an 18-month prognosis.

Intervention Type
Other

Primary outcome measure
Death or hospitalization for heart failure (HF) in the 18 months following the hospitalization for acute heart failure (AHF), taken from medical records

Secondary outcome measures
1. Cytokine profile, inflammation markers (CRP, IL-6 and other cytokines) in the acute intrahospital phase and at 6 weeks (F6w), 6 months (F6), 12 months (F12) and 18 months (F18) after hospitalization for AHF

2. Adaptive immune response pattern (heart-reactive antibodies) at F6w, F6, F12 and F18: cellular immunophenotypes, anti-myocardial antibody titres and quality, frequencies and differentiation of heart-reactive T cells
3. Cardiac structure and function (echocardiography: LV volume, LVEF, e´) at F6w, F6, F12, and F18
4. Heart failure severity (NYHA, NT-proBNP, 6-min walking distance) at F6w, F6, F12, and F18
5. Hospitalization (for worsening HF and all-cause, respectively) at F6, F12 and F18, taken from medical records
6. Death (cardiac and all-cause, respectively) at F6, F12 and F18, taken from medical records

Overall study start date
08/04/2021

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Hospitalization for AHF (consecutive patients, Dept. of Internal Medicine I)
2. Age ≥18 years
3. Written informed consent
4. Willingness to attend planned follow-up visits at the Comprehensive Heart Failure Center (CHFC)
5. Life expectancy ≥6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
381

Key exclusion criteria
1. High urgency listing for heart transplant
2. High output failure
3. Left ventricular assist device (LVAD) implanted/planned

Date of first enrolment

01/02/2022

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Würzburg
Oberdürrbacher Str. 6
Würzburg
Germany
97078

Sponsor information

Organisation
University Hospital Würzburg

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Sponsor type
Hospital/treatment centre

Website
https://www.ukw.de

Funder(s)

Funder type
Research organisation

Funder Name

German Research Foundation (DFG) within the Comprehensive Research Center 1525 'Cardio-immune interfaces' (453989101, project C5)

Results and Publications

Publication and dissemination plan
Design and first results - submitted

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study can be made available upon request from Caroline Morbach (Morbach_C@ukw.de).

IPD sharing plan summary
Available on request