

Role of heart-reactive antibodies in heart failure

Submission date 06/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/02/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

110 years

Sex

All

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

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

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