

# Acute Heart Failure (AHF) Registry Würzburg

<b>Submission date</b> 04/08/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2014	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/09/2021	<b>Condition category</b> 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

Documented information about the outcome of treatments for patients with acute heart failure (AHF) during their stay in hospital and during their follow-up visits is very scarce. Further, no up-to-date data are available on in-patient clinical profiles in the critical stages. Follow-up data are lacking, including documentation of heart function that can help in the understanding of the type and severity of heart failure, modern treatment patterns after a hospitalization for AHF, management of risk factors and associated diseases (e.g. kidney failure or anaemia) and information on type and rates of complications. It is also unknown how many patients after a hospital admission for acute heart failure will, in the long run, develop advanced heart failure. The AHF registry is an initiative of the Comprehensive Heart Failure Center Würzburg. It is a forthcoming short- and long-term registry of HF patients, enrolled at the time of hospitalization for AHF, which will help to address the above listed knowledge gaps. The AHF registry will be capable of identifying unmet medical, psychosocial and palliative needs, monitor the impact of new drug-related as well as surgical treatment options for HF, and direct future HF research.

### Who can participate?

Adult patients who are hospitalized for acute heart failure.

### What does the study involve?

The study involves a complete data collection during the hospital stay and regular follow-up visits up to 5 years to assess the patients' health status. This registry is necessary to document the natural history of AHF, and associated long-term HF treatment patterns including re-hospitalization rates, specific treatment patterns for certain risk factors and other diseases that can be associated with HF, clinical outcomes, quality of life (QoL), brain function, depression and standardized evaluation of palliative requirements. This 'real world' data collection study will not interfere with the usual care of patients, and will not lead to specific diagnostic procedures or treatments. Study data will be collected during routine visits.

### What are the possible benefits and risks of participating?

Patients might benefit from regular examinations; however, there is no immediate benefit. The results of the data collection in the registry might in future contribute to a better diagnosis and treatment of acute heart failure. There are no risks to participating.

Where is the study run from?  
University Hospital in Wuerzburg, Germany.

When is the study starting and how long is it expected to run for?  
August 2014 until August 2025.

Who is funding the study?  
The Federal Ministry of Education and Research (Germany).

Who is the main contact?  
Prof. Dr med. C. Angermann  
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**Study website**  
<http://www.chfc.ukw.de/en/research/project-areas/project-area-g.html>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Prospective cohort study on etiology, clinical Features, costs, palliative needs and outcomes in acute heart failure

**Acronym**

### **Study objectives**

1. Analyses of the data will significantly improve the pathophysiological knowledge about AHF and in particular about the early phase after cardiac decompensation, worsening, progressive and advanced HF. Further, it will provide by prospective assessment of treatment efficacy a rational basis for future differential treatment allocation in patients with AHF and advanced HF considering also HF etiology and course.
2. Since consecutive patients will be recruited on a 7 day/24 hour basis, a representative profile of the various etiologies and clinical representations of AHF will for the first time be generated in the frame of the German healthcare system.
3. Data generated from this study can be used to better define significant prognostic characteristics and guide short-term management and maintenance treatment decisions.
4. With this study it will be possible to identify so far unmet needs of the participants.
5. Data generated from the study will allow monitoring the impact of novel pharmacological and surgical HF treatment options on the clinical short- and long-term course and direct future HF research.
6. Systematic longitudinal characterization of the clinical profile of advanced HF patients including documentation of outcome data in relation to applied treatment modalities will generate reliable information on the natural course of the disease as well as on the short- and long-term effects of specific pharmacological, interventional and surgical procedures in these 'real life' patients beyond the data available from randomized clinical trials.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of the University of Wuerzburg, July 2014, ref. 55/14

### **Study design**

Prospective cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Acute heart failure

## **Interventions**

There is no intervention in this study. The data collection for the AHF Registry Würzburg does not interfere with any routine diagnostic or therapeutic procedures. There are no additional study-related examinations or procedures.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Incidence of post-discharge events (re-hospitalization and cause-specific death) during the observation period

## **Secondary outcome measures**

1. Proportion of patients with HFrEF versus HFpEF at the time of the index hospitalization
2. Proportion of patients with HFrEF versus HFpEF versus other aetiologies including reversible HF (e.g. arrhythmogenic) at the time of discharge from hospital after the index hospitalization
3. Proportion of patients with de novo versus decompensated chronic HF at the index hospitalization
4. Frequency of diagnosis of different HF etiologies at the time of index hospitalization
5. Time course of re-hospitalization events (all-cause and HF-related, duration of hospital stays and time intervals between consecutive re-hospitalization events) and incidence of cause-specific death after the index hospitalization
6. Time alive and out of hospital
7. Prevalence of advanced HF at index hospitalization
8. Incidence of advanced HF during follow-up
9. Clinical course and outcomes of patients with advanced HF according to different treatment patterns (e.g. surgical versus medical only)
10. Incidence of the transition from HFrEF to HFpEF and vice versa during long-term follow-up
11. Prevalence, severity and correlates of anxiety, depression, cognitive impairment, and impairment of quality of life during the index hospitalization and during long-term follow-up
12. Differential impact of co-morbidities on short-term and long-term outcomes

## **Overall study start date**

01/08/2014

## **Completion date**

31/08/2025

## **Eligibility**

### **Key inclusion criteria**

1. Age >18 years
2. Hospitalization with AHF (de novo/decompensated chronic HF) according to the clinical judgment of the responsible physician
3. Written informed consent

## **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

1000

**Key exclusion criteria**

1. Cardiogenic shock
2. High output heart failure
3. On waiting list for urgent HTX

**Date of first enrolment**

01/08/2014

**Date of final enrolment**

31/08/2020

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

**Straubmühlweg 2a**

Wuerzburg

Germany

97078

## **Sponsor information**

**Organisation**

University of Würzburg (Universitätsklinikum Würzburg) (Germany)

**Sponsor details**

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**Sponsor type**

University/education

**ROR**

<https://ror.org/03pvr2g57>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration