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Acute Heart Failure (AHF) Registry Würzburg

Submission date
04/08/2014

Recruitment status
No longer recruiting

Registration date
16/10/2014

Overall study status
Ongoing

Last Edited
16/09/2021

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 Wuerzburg. 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

AHF Registry Würzburg

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)

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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