

Acute heart failure-voice

Submission date 12/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/04/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/07/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The Acute Heart Failure (AHF)-Voice study aims to explore the relationship between congestion and voice alterations in patients with AHF to see if it reflects their clinical condition. The study will address the following key questions:

1. What are the characteristics and determinants of vocal alterations in patients with AHF?
2. To what extent do these vocal alterations correlate with the patient's clinical status during an AHF episode?
3. To what extent are vocal biomarkers sensitive to changes over time, and how do they compare to established clinical parameters in HF such as quality of life or NT-proBNP levels?
4. Can specific vocal biomarkers or combinations be mapped to different HF phenotypes?
5. Are vocal biomarkers associated with patient prognosis?
6. Are voice alterations in patients with AHF associated with pathophysiological changes, such as vocal fold edema, that affect vocal fold oscillation?

Who can participate?

Patients aged 18 years and over who are hospitalized at the University Hospital Würzburg for AHF

What does the study involve?

Detailed clinical, echocardiographic and voice assessment at baseline, 6 weeks and 6 months after hospitalization.

What are the possible benefits and risks of participating?

By providing optimal management opportunities this structured approach will likely benefit also individual study participants. Since this study is purely descriptive and standard medical care will not be affected, there are no study-specific risks for patients.

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?

February 2022 to July 2025

Who is funding the study?

The study is funded by the German Ministry of Research and Education within the UNISONO Consortium

Who is the main contact?

Dr Fabian Kerwagen, MPH, Kerwagen_F@ukw.de

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

16SV8877

Study information

Scientific Title

Acute heart failure voice analysis prospective cohort study

Acronym

AHF-Voice

Study objectives

The hypothesis is that volume overload and recompensation in patients with AHF are associated with voice alterations reflective of changes in clinical status.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 16/03/2023, Medical Ethics Committee at the Julius-Maximilians-University Würzburg (Josef-Schneider-Str. 4, C15, Würzburg, 97080, Germany; +49 (0)931 31 48315; ethikkommission@uni-wuerzburg.de), ref: 245/22

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 6 months. The trajectory of voice alteration will be tracked through daily voice recordings. Follow-ups will be conducted at 6 weeks and 6 months after decompensation.

Intervention Type

Other

Primary outcome(s)

Change of vocal biomarker during an acute heart failure episode at index hospitalization (Baseline), assessed through daily voice recordings

Key secondary outcome(s)

1. Change in the vocal biomarker during the 6-month observation period, assessed through daily voice recordings.
2. Type and prevalence of vocal cord dysfunction assessed by video-stroboscopy during an AHF episode (Baseline), 6 weeks (F6w), 6 months (F6m) after hospitalization for AHF
3. Cardiac structure and function, assessed by echocardiography at Baseline, F6w, F6m
4. Heart failure severity (NYHA, NT-proBNP, 6-min walking distance) at Baseline, F6w, F6m
5. Pulmonary function assessed by pulmonary function tests at F6w, F6m
6. Quality of life assessed by questionnaires at Baseline, F6w, and F6m
7. (Re-)Hospitalization (for worsening HF and all-cause, respectively) at F6w and F6m, taken from medical records
8. Death (cardiac and all-cause, respectively) at F6w and F6m, taken from medical records

Completion date

31/07/2025

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

Sex

All

Total final enrolment

131

Key exclusion criteria

1. High output heart failure
2. Cardiogenic shock
3. High-urgency listing for heart transplant
4. Left ventricular assist device (LVAD) implanted/planned
5. History of vocal fold disorder or vocal fold surgery

Date of first enrolment

14/04/2023

Date of final enrolment

03/12/2024

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

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study can be made available upon reasonable request from Fabian Kerwagen, Kerwagen_F@ukw.de.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		02/05/2025	07/07/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes