# Acute heart failure-voice

Submission date	Recruitment status	☐ Prospectively registered
12/02/2025	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
03/04/2025	Completed	Results
Last Edited	Condition category	[] Individual participant data
<b>9</b> 3	Circulatory System	[X] 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

#### Contact name

Dr Fabian Kerwagen

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

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

# Sponsor information

#### Organisation

University Hospital Würrzburg

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Bundesministerium für Bildung und Forschung

#### Alternative Name(s)

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
Interim results article

Date created Date added Peer reviewed? Patient-facing?

02/05/2025 07/07/2025 Yes

No

Details

 Participant information sheet
 11/11/2025
 11/11/2025
 No
 Yes

 Study website
 11/11/2025
 11/11/2025
 No
 Yes