

# Acute heart failure-voice

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

## Plain English Summary

### 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

### **Study website**

<http://www.unisono-projekt.com/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Dr Fabian Kerwagen

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

16SV8877

## **Study information**

### **Scientific Title**

Acute heart failure voice analysis prospective cohort study

### **Acronym**

AHF-Voice

### **Study hypothesis**

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

### **Secondary study design**

Cohort study

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

Hospital, Medical and other records

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

Diagnostic

### **Participant information sheet**

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

### **Condition**

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 measure**

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

### **Secondary outcome measures**

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

**Overall study start date**

01/02/2022

**Overall study end date**

31/07/2025

## Eligibility

**Participant inclusion criteria**

1. Hospitalization for AHF (consecutive patients, Dept. of Internal Medicine I)
2. Age  $\geq 18$  years
3. Written informed consent
4. Willingness to attend planned follow-up visits at the Comprehensive Heart Failure Center (CHFC)
5. Life expectancy  $\geq 6$  months

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

131

**Total final enrolment**

131

**Participant 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

**Recruitment start date**

14/04/2023

**Recruitment end date**

03/12/2024

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

**University Hospital Würzburg**

Oberdürrbacher Str. 6

Würzburg

Germany

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## Sponsor information

**Organisation**

University Hospital Würzburg

**Sponsor details**

Comprehensive Heart Failure Center, Am Schwarzenberg 15

Würzburg

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97080

+49 (0)931 201 46363

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.ukw.de>

## 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

**Publication and dissemination plan**  
Planned publication in a peer-reviewed journal. Study design and baseline characteristics - submitted

**Intention to publish date**  
01/03/2025

**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