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Acute heart failure-voice

Submission date
12/02/2025

Recruitment status
No longer recruiting

Registration date
03/04/2025

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Circulatory System

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

Study website
http://www.unisono-projekt.com/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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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 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

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

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 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

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
131

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 Würrzburg

Sponsor details
Comprehensive Heart Failure Center, Am Schwarzenberg 15
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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

Study outputs

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