Pre-Symptomatic Detection of Impending Decompensation in Heart Failure through Voice Data (PRE-DETECT-HF)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON57126

Source
ToetsingOnline

Brief title
PRE-DETECT-HF

Condition

- Heart failures

Synonym
heart congestion, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Noah Labs UG
Source(s) of monetary or material Support: EIT Health - Flagship program - Europese Unie

Intervention

Keyword: congestion, Heartfailure, voice detection

Outcome measures

Primary outcome

The primary objective is to validate the voice-based decompensation prediction software in predicting heart failure deterioration in patients discharged after admission due to decompensated heart failure.

The primary endpoint of the study is deterioration of heart failure.

Deterioration of heart failure is defined as:

- Cardiovascular mortality

- Heart failure related hospitalisation

- Intensifying heart failure therapy due worsening of heart failure according to the assessment of the investigators and/or treating physician, i.e. typically intensifying diuretic therapy (either iv. or for at least 2 days), but may also include e.g. MRA or SGLT2-inhibition. Uptitration of therapy as standard HF treatment is not considered as endpoint.

Secondary outcome

There are two main seconday objectives in this study:

Firstly, the study will systematically evaluate both patient adherence to, and the user-friendliness of the newly developed software application. It is also relevant in this context to evaluate the effect of Quality of Life on the adherence and usability (15).

Secondly, the association of voice outcomes with well-established and novel

blood biomarkers will be investigated.

To achieve the secondary objective, the study will assess the following endpoints:

• Adherence will be evaluated by registring the number and percentage of days on which at least one voice recording is transmitted to the application

• Usability will be evaluated using questionnaires and interviews, where user experiences and expectations could be analysed.

• The influence of Quality of Life on adherence and usibility will be assessed by combining the Kansas City Cardiomyopathy Questionnaire (KCCQ) (15) outcomes with the quantitative results of adherence, which could be substatiated using usibility outcomes.

And;

• Laboratory results (if clinically indicated, results of clinical routine will be used; otherwise, the blood biomarkers will be obtained as part of the study): creatinine, potassium, sodium, urea, NT-proBNP

Study description

Background summary

Heart failure (HF) is a common chronic disease that contains the risk of imminent volume overload, called decompensation. Symptoms usually occur late during the course of decompensation, leaving insufficient time to effectively intervene. Voice-based digital biomarker may detect imminent deterioration significantly earlier without the requirements of implantation of invasive devices such as CardioMEMS

Study objective

The main objective of the study is to optimize the use and user-friendliness of the voice analysis program, which could potentially help with the early detection of acute deterioration in heart failure. Hopefully, we can develop a technique that enables quicker intervention during deterioration. By adjusting medication more rapidly, the patient may be in the future hospitalized less frequently, once proven in RCT.

Study design

This study will be performed at three sites (Barcelona, Zuyderland, Maastricht). Patients admitted to hospital with Acutely Decompensated HF (ADHF) will be included in the study prior to discharge from the hospital. Patients will be equipped with a smartphone or tablet (if required an additional external microphone) and the pre-installed Noah Labs patient application (both provided by Noah Labs to the study sites). The app will include also some questions regarding symptoms of HF. During admission while still volume overloaded, patients will perform the first voice recordings. The recording immediately prior to discharge, i.e. when completely recompensated, will subsequently be considered the baseline recording. The recording from decompensation while still volume overloaded until recompensation will be used to personalize the individual voice pattern, which will be the refence recording. In their own homes, patients will continue to record structured voice samples with a combination of pre-defined text samples and a variable content to avoid boredom daily for about 2 minutes. The variable content will be related to general worth knowing facts. They will also answer the questions regarding eventual HF related symptoms (standard care). All voice samples and the answers to the symptom questions will be transmitted to the Noah Labs server for analysis and will be compared to the reference sample that was recorded at the day of discharge of the respective patient.
In addition, investigators at the three clinical sites will be provided access to the Noah Labs healthcare provider (HCP) platform. If certain thresholds are exceeded regarding standard care (e.g. increase in shortness of breath, peripheral oedema), HCP will receive notifications about the findings. It is also possible for HCP*s to follow daily substantive data.
The study will be 6 months with fixed evaluation at months 1, 3 and 6. At month 1, only a remote contact (by telephone) will take place. After discharge, the study will be conducted in the outpatient departments of the study sites. The patients will be seen by a physician knowledgeable of HF that is part of the study team (investigator). Additional contacts with healthcare providers will be possible as clinically required.

Intervention

Recording of structured voice samples with a combination of pre-defined text samples and a variable content to avoid boredom daily for about 2 minutes. The variable content will be related to general worth knowing facts. In addition,

standard eHealth in both groups (i.e. questions regarding HF symptoms and body weight). Based on this monitoring, notifications will be sent to study centres in case of imminent decompensation. Physician will then intervene with standard HF treatment to avoid decompensation (mainly diuretics), according to current HF guidelines.

Study burden and risks

There is some additional burden for the patient due to the fact that they need to spend 2-5 minutes daily using the app. Every two weeks, patients will also need to complete an additional questionnaire with 3-8 questions on various topics (e.g., expectations, user-friendliness of the app, acceptance of voice analysis monitoring) via the app. Additionally, 1 extra blood sample will be collected at each visit.

There is no direct risk associated with using the app. Although an increase in medication therapy based on deterioration of heart failure has side effects, such as worsening kidney function, this is generally the case for the treatment of heart failure and not specific to this study. The associated risks of worsening heart failure are also estimated to be higher than the side effects of the medication therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Informed consent provided
- Currently hospitalized for acutely decompensated HF or de-novo HF
- Age: >18 years

Exclusion criteria

- Inability to provide consent
- Pregnancy
- Life-expectancy < 1 year due to a condition other than HF
- Planned cardiac intervention within the next 6 months (e.g. valve replacement, bypass surgery)
- Disabling mental diseases (e.g., Alzheimer's disease)
- Symptoms mainly caused by chronic disease other than HF such as chronic obstructive pulmonary disease
- Inability to use a smartphone or a tablet computer despite support by informal caregiver if required
- Insufficient knowledge of local language (Dutch, Spanish or Catalan)
- Previous operations on organs involved in generation of voice (vocal tract, vocal folds, etc.)
- Participation in another interventional study within 30 days of inclusion

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-09-2024
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Noah labs telemonitoring
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-11-2024
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86154.096.24