Radio-frequency sensing: non-invasive monitoring of heart failure progression

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Primary objective: Determine correlation between RFS parameters (5 independent signal characteristics) and non-invasive hemodynamic parameters (estimated left ventricular end diastolic pressure, left ventricular ejection fraction, left ventricular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON56751

Source
ToetsingOnline

Brief title
AIM-HF study

Condition

- Heart failures

Synonym
decompensation, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: De Hartstichting;HealthHolland,PrecorDx B.V.

Intervention

Keyword: heart failure, Non-invasive, prevention, RF sensing

Outcome measures

Primary outcome

Primary endpoint 1: correlation between RFS parameters and non-invasive hemodynamic parameters in cardiovascular patients.

• Key parameters RFS: signal amplitude, area under the curve, average value, frequency, spectral content

• Key parameters non-invasive hemodynamic measurements: estimated left ventricular end diastolic pressure, left ventricular ejection fraction, left ventricular stroke volume, right ventricular ejection fraction, right ventricular stroke volume

Secondary outcome

Secondary endpoint 1: correlation between RFS parameters and non-invasive hemodynamic parameters in cardiovascular patients.

• Key parameters RFS: signal amplitude, area under the curve, average value, frequency, spectral content

• Key parameters invasive hemodynamic measurements: atrial pressure, right ventricular pressure, pulmonary capillary wedge pressure and pulmonary artery pressure, diastolic/systolic/mean

Secondary endpoint 2: Difference in RFS parameters in cardiovascular patients before and after treatment

• Key parameters RFS: signal amplitude,area under the curve value, average

value, frequency

Study description

Background summary

Heart failure is a major healthcare burden with high incidence and mortality (Groenewegen et al., 2020). An important challenge in heart failure treatment is monitoring the progression of chronic heart failure and therefore required optimization of medication. If heart failure develops from a chronic to an acute state and medication is not adjusted properly, patients need to be admitted to the hospital with very severe symptoms such as lung oedema. Currently more than 50% of all patients with heart failure gets readmitted to the hospital within 6 months after treatment (Desai and Stevenson, 2012) when heart failure transitions from chronic compensated to an acute decompensated state. Associated with hospitalization are increased mortality rates up to 10% (McDonagh et al., 2021), irreversible disease progression and high costs. Hospitalization is the driving factor behind the enormous economic costs of heart failure ($ 65 billion per year worldwide, (Urbich et al., 2020)).
Tracking heart failure progression requires repeated (home) monitoring of cardiac contractile function and left ventricular filling pressure, which is not possible with current non-invasive technology. Available non-invasive methods such as MRI or TTE can only be used by expert and are not cost-effective. Previously we developed RF sensing, a novel method that non-invasively measures hemodynamic parameters such as stroke volume, ejection fraction, ejection time with radio-antennas (Steensma et al., 2022) which represent the contractile function of the heart.

The concept of RF Sensing has been tested and validated in healthy controls in an experimental setting, but not yet in larger groups of healthy subjects or patients with cardiovascular disease. The overall aims of this study are to demonstrate that with RF Sensing, it is possible to measure hemodynamic parameters with comparable precision and accuracy as TTE and MRI and to show that differences in RFS signals are observable between compensated and decompensated heart failure, as well as healthy controls.

Based on the expected correlation between RFS and ground truth TTE/MRI measurements of hemodynamic parameters, we expect that it is necessary to compare TTE and RFS in at least 50 subjects.

This study is initiated by the sponsor UMC Utrecht. In addition, the study is co-funded by PrecorDx, a spinoff company of UMC Utrecht that aims to commercialize the RF Sensing technology. Dr. Steensma, a sub-PI of the study, is a co-founder and shareholder of PrecorDx. Dr. Tjong, a sub-PI of the study,

is the spouse of a co-founder and shareholder of PrecorDx.

Study objective

Primary objective: Determine correlation between RFS parameters (5 independent signal characteristics) and non-invasive hemodynamic parameters (estimated left ventricular end diastolic pressure, left ventricular ejection fraction, left ventricular stroke volume, right ventricular ejection fraction, right ventricular stroke volume) in a group of cardiovascular patients and healthy controls with a wide range of anatomical variation and pathological conditions.

Secondary objective 1: Determine the correlation between RFS parameters and invasive hemodynamic parameters (atrial pressure, right ventricular pressure, pulmonary capillary wedge pressure and pulmonary artery pressure, diastolic/systolic/mean) in cardiovascular patients.

Secondary objective 2: Explore the sensitivity of RFS parameters to treatment effects.

Study design

This is an interventional study. The study will take place between 1 December 2023 (target start date) and 30 November 2026 (total duration 36 months) at the Cardiology and Radiology department of the University Medical Center Utrecht and the Cardiology department of the Amsterdam University Medical Center. The study is a multi-center study, to ensure sufficient patients can be included, and to ensure that patients with various types of heart failure can be included. Data collection will take place at these same centers. Analysis will be performed by researchers from the UMC Utrecht Radiology and Cardiology departments.

To achieve sufficient statistical power for our primary objective, we will include 40 patients and 10 healthy controls.

Intervention

Participants undergo the following measurements, outside of standard care:

- TTE and RF Sensing measurement.
- MRI and RF Sensing measurement.
- RF Sensing measurement during catheterization (only if catheterization is part of standard care).
- During the RF Sensing measurement, ECG and arm cuff blood pressure is measured.
- Patient fill out a short questionnaire about the comfort of RFS measurements.

Study burden and risks

Subjects participating in this study will derive no direct benefit from the study. However, the outcome of this study will aid in improving diagnosis and treatment of heart failure, which may improve consequent individual treatment possibilities.

In case of unexpected findings during the TTE or MRI, the treating cardiologist will be warned.

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

• Patients planned for a right heart catheterization with invasive pressure measurement
• Patients that are screened for a left ventricular assist device or a heart transplant
• Patients that have recently received a heart transplant
• Patients with NYHA class II-IV heart failure, preserved as well as reduced ejection fraction
• Patients with pulmonary hypertension
• Patients with known (risk of) chemotherapy induced cardiac dysfunction
• Patients with any cardiac arrhythmia
• Patients with an implantable pulmonary artery pressure sensor
•Cardiovascular patients on the intensive care unit or cardiac care unit undergoing daily hemodynamic measurements

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Patients that have an active implant (cardiac implant such as CRT, ICD, LVAD, or any other active implants such as insulin pump, cochlear implant or neural stimulator) that cannot be switched to passive or sensing mode.
• Patients is expected to die within 6 months from any nonrelated disease
• Patient that are not physically able to undergo TTE, MRI and/or RFS measurements at the time of inclusion

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-03-2024

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-07-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL82703.041.23