HaFaC study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28510

Source
Nationaal Trial Register

Brief title
HaFaC

Health condition

Heart Failure
NYHA classification

Sponsors and support

Primary sponsor: Catharina Ziekenhuis Eindhoven
Source(s) of monetary or material Support: Catharina Ziekenhuis Eindhoven
Catharina Onderzoeksfonds

Intervention

Outcome measures

Primary outcome

Main study parameters are echocardiographic structural and functional measures, blood marker levels, QOL scores, 6MWT (and when measured (spiro-)ergometry) performance scores, (24 hour) ECG-derived variables, 24 hour blood pressure measurements, and PPG and accelerometer data of patients with HF.

The main study endpoint is an objective classification model for HF patients where the model output is represented as a scale of HF disease severity reflected by clinically relevant, objective measures. The study endpoint for the participant is the composite endpoint of all-cause
mortality, heart transplantation or Left Ventricular Assist Device (LVAD) implantation.

Secondary outcome

Secondary endpoints are:

• expert-based NYHA classification

• questionnaire-based NYHA classification

• QOL (MLHFQ and SF-36 questionnaires)

• structural and functional characteristics of the heart through echocardiography (e.g. left ventricular dimensions and LVEF)

• biomarker levels (e.g. NT-proBNP)

• simultaneous registered ECG and blood pressure signals and consequential characteristics (e.g. heart rate variability)

• PPG and accelerometer signals

• exercise tolerance according to 6MWT and (spiro-)ergometry (e.g. percentage capacity)

• hospitalization for HF

• LVAD implantation

• heart transplantation

• mortality

Study description

Background summary

Heart failure (HF) is a complex clinical syndrome of signs and symptoms due to a structural or functional abnormality of the heart leading to

inadequate pumping function. The functional state of the patient, i.e. the ability to do the

daily activities, plays an important role in HF.

Classification of HF using the New York Heart Association (NYHA) is based on symptoms and perception of exercise tolerance. In addition to

the assessment of severity of the symptoms upon diagnosis, the NYHA classification is also used to monitor response to treatment and is a

predictor of mortality. Although the NYHA classification itself has proved to be clinically useful, the way of classifying HF patients, based on the

patient’s and physician’s perception of exercise intolerance, is inaccurate. Therefore, a need is seen in a new classification model for HF

patients which is based on multiple, objective, and clinically relevant measures covering multiple aspects of the HF syndrome.

The primary objective of this study is to develop an objective, clinical relevant classification model of disease severity for patients with HF

based on an extensive, complete dataset of patients with HF. The study is a prospective, non-randomized, observational, single-center study. A cross-section of the outpatient HF population in the cardiology department will be included (n=278).

Main study parameters are echocardiographic structural and functional measures, blood marker levels, QOL scores, 6MWT (and when

measured (spiro-)ergometry) performance scores, (24 hour) ECG-derived variables, 24 hour blood pressure measurements, and PPG and accelerometer data of patients with HF.

Study objective

The primary objective of this study is to develop an objective, clinical relevant classification model of disease severity for patients with HF based on an extensive, complete dataset of patients with HF.

Study design

baseline, 6 months, 12 months

Intervention

Observational

Contacts

Public
Saskia van Loon
Eindhoven
The Netherlands
Scientific
Saskia van Loon
Eindhoven
The Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must have (suspected) heart failure (based on ESC guidelines 2016), is scheduled for a cardiac ultrasound, has not had cardiothoracic surgery within 90 days prior to moment of inclusion, must have the minimum age of 18 years, and must be able to provide informed consent.

Exclusion criteria

A potential subject will be excluded from the study if the patient is pregnant or when the subject has terminal heart failure with a life expectancy of several weeks.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2017
Enrollment:	278
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-08-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45646
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7268
NTR-old	NTR7466
CCMO	NL60579.100.17
OMON	NL-OMON45646

Study results