Heart Failure Classification based on Objective Measurement Data

Published: 02-06-2017
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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.

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

Summary

ID

NL-OMON45646

Source
ToetsingOnline

Brief title
HaFaC study

Condition

- Heart failures

Synonym
Cardiac Decompensation, Heart Failure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Classification, Data Mining, Heart Failure

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.

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

The study is a prospective, non-randomized, observational, single-center study.

Study burden and risks

In this study, 278 patients will be included that represent a cross-section of the outpatient heart failure patient population in the Cardiology department of the Catharina Hospital. All of these patients will undergo multiple measurements at the Catharina Hospital during the patient*s outpatient visit, i.e. echocardiography, blood withdrawal for biomarker level analysis, and QOL assessment through questionnaires. Additionally, in a subgroup of participants ergometry or spirometry and simultaneous ECG, blood pressure, PPG and accelerometer data of participating patients will be collected.

The risks associated with this study are negligible. The study consists of measurements that are part of standard clinical care. Only the combination of all the measurements is unusual in the outpatient clinical care. Since the data obtained by this study may result in a method to classify and monitor patients with heart failure in an objective manner in the future, and since the manner in which the data is obtained is identical to already delivered standard care (whether or not in the combination, as done in this study), we believe that this research is warranted.

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

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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2017
Enrollment:	278
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28510
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60579.100.17
OMON	NL-OMON28510