HaFaC study

Gepubliceerd: 14-08-2018 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28510

Bron
Nationaal Trial Register

Verkorte titel
HaFaC

Aandoening

Heart Failure
NYHA classification

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis Eindhoven
Overige ondersteuning: Catharina Ziekenhuis Eindhoven
Catharina Onderzoeksfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

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

Doel van het onderzoek

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.

Onderzoeksopzet

baseline, 6 months, 12 months

Onderzoeksproduct en/of interventie

Observational

Contactpersonen

Publiek

Saskia van Loon
Eindhoven
The Netherlands

Wetenschappelijk

Saskia van Loon
Eindhoven
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-12-2017
Aantal proefpersonen:	278
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45646

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten