Monitoring of patients with chronic heart failure with a wrist-worn data logger.

Gepubliceerd: 06-11-2020 Laatst bijgewerkt: 13-12-2022

We hypothesize that several parameters, measured with a wrist-worn data logger, will be predictive for a heart failure event. Parameters which are taken into account are: heart rate, activity count, energy expenditure, but also parameters which are...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21559

Bron
NTR

Verkorte titel
INNOVATE-HF

Aandoening

Heart failure regardless of etiology and heart failure type

Ondersteuning

Primaire sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the predictive value of different physical activity parameters, measured with a wrist-worn data logger, in deterioration of heart failure.

Toelichting onderzoek

Achtergrond van het onderzoek

To improve telemonitoring strategies in patients with chronic heart failure, there is a need for novel parameters and technologies to monitor these patients. Monitoring of physical activity and other parameters such as heart rate variability and sleep, might serve as a useful adjunct to the regular parameters being monitored. This is supported by previous studies in patients with an implantable cardioverter defibrillator (ICD), which showed that ICD parameters such as heart rate, heart rate variability and activity are predictive for heart failure readmissions. However, a substantial part of HF patients do not have an ICD or one that features activity monitoring. Therefore the aim of the present study is to evaluate the predictive value of several parameters measured with a wrist-worn data logger for deterioration of heart failure.

Doel van het onderzoek

We hypothesize that several parameters, measured with a wrist-worn data logger, will be predictive for a heart failure event.

Parameters which are taken into account are: heart rate, activity count, energy expenditure, but also parameters which are not related to physical activity, such as heart rate variability, respiratory rate and sleep parameters.

A heart failure event is defined as a hospital readmission or an uptitration of oral diuretics at the outpatient clinic, due to decompensated heart failure.

Onderzoeksopzet

Continuous data (24/7) for a period of 3 months after hospital discharge due to an episode of acute decompensated heart failure.

Onderzoeksproduct en/of interventie

This is a single-center, prospective exploratory proof of concept study.

Patients who are admitted to Máxima Medical Centre due to an episode of decompensated heart failure, and who are meeting the other in- and exclusion criteria, are asked to participate in the present study.

If they consent to participate, they will be asked to wear a non-obtrusive, wrist-worn data logger (Philips Netherlands B.V.) for a period of 3 months from the moment of discharge from the hospital. They will be asked to wear the data logger 24/7 to gather photoplethysmography (PPG) and accelerometry data. These data are translated in several parameters such as: heart rate, heart rate variability, activity count, activity type, energy

expenditure, respiratory rate and sleep data.
Patients do not receive feedback or coaching based on the recorded data. After three months the patient will hand in the data logger.

During follow-up the medical records of the participants will be periodically checked to report recurrent heart failure events. A heart failure event is defined as a hospital readmission, or an uptitration of oral diuretics at the outpatient clinic, due to decompensated heart failure.

Contactpersonen

Publiek

Maxima Medical Centre
Cyrille Herkert

+3140 888 8220

Wetenschappelijk

Maxima Medical Centre
Cyrille Herkert

+3140 888 8220

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed with heart failure (regardless of heart failure type and etiology)
2. Admitted to the hospital due to acute decompensated heart failure
3. Age ≥ 18 years
4. Able to speak and read the Dutch language
5. Willing and able to provide informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Permanent atrial fibrillation

2. Not able or willing to wear a wrist-worn data logger on a daily basis (for example due to work related obligations)
3. Major planned (cardiac) surgery in the upcoming 3 months
4. Not able to perform daily physical activity due to orthopedic of neurological disease
5. Bed/chair ridden patients
6. Presence of wounds, injuries or infectious diseases on the skin where the wrist-wearable device will be placed

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-11-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9038
Ander register	METC MMC (study received a waiver that ethical approval was not required) : N19.049

Resultaten