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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21559

Source
NTR

Brief title
INNOVATE-HF

Health condition

Heart failure regardless of etiology and heart failure type

Sponsors and support

Primary sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

-

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Not applicable

Application type:	Not applicable

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

Study results