The Kinocardiograph for assessment of fluid status in patients with heart failure

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Changes in cardiac KE are correlated with changes in volume status in patients with acute decompensated heart failure.

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

Samenvatting

ID

NL-OMON26847

Bron
NTR

Verkorte titel
Kino-ADHF

Aandoening

Heart failure (regardless of type and etiology)

Ondersteuning

Primaire sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the correlation between changes in KE (mJ/heartbeat) and changes in fluid status (based on diameter and percentage collapse of the IVC).

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic heart failure (CHF) is a common cardiac condition with a high morbidity and mortality. CHF is often associated with episodes of acute decompensated heart failure (ADHF) which may lead to hospital admissions. This in turn leads to an impaired quality of life and also a major economic burden. Telemonitoring can contribute to early detection of ADHF, thereby providing early intervention which may reduce the patients' disease burden. Traditionally, telemonitoring in CHF consists of monitoring vital parameters (such as weight, blood pressure, heart rate), and physical complaints related to CHF. However these parameters change relatively late in the cascade of pathophysiological events leading to ADHF. Therefore there is a need for monitoring of additional parameters, preferably ones that changes earlier in this cascade. This can be achieved by invasive monitoring of pulmonary atery pressure or parameters derived from ICD's. Non-invasive monitoring of parameters closely related to hemodynamic state and cardiac filling pressures are not available yet.

Therefore the aim of the present study to evaluate whether changes in cardiac kinetic energy (KE), measured with a non-obtrusive, non-invasive device (Kinocardiograph (KCG)), are related to changes in fluid status in patients with acute decompensated heart failure.

The KCG consists of 2 small micro-electrical-mechanical-system (MEMS) accelerometers which are attached to the body with ECG patches. One sensor is placed on the sternum and measured seismocardiographic signals, and the other sensor is placed on the lower back, measuring ballistocardiographic signals. These can be translated to cardiac kinetic energy.

Doel van het onderzoek

Changes in cardiac KE are correlated with changes in volume status in patients with acute decompensated heart failure.

Onderzoeksopzet

Daily measurements are performed:
1. A 90 second KE measurement, with the KCG
2. Diameter and percentage collapse of the IVC, with echocardiography.

Both measurements are performed within a patient on a daily basis. The measurements start at hospital admission for ADHF and are continued until discharge from the hospital (which is decided by the cardiologist at the ward). Therefore the number of measurements will vary for each participant, depending on the number of days admitted to the hospital.

Onderzoeksproduct en/of interventie

Patients who meet the inclusion criteria are asked by the doctor on the emergency

department, whether they give permission to be contacted in person by the coordinating investigator. Subsequently the investigator will provide the patient with verbal and written information about the study. The patient will be asked to make a decision about participation within 24 hours, because iv diuretic therapy will start directly after admission.

If a patients consents to participate, he will receive usual treatment for ADHF (with iv diuretics). During admission daily study related measurements will follow. These measurements consist of a 90 seconds KCG reading to determine cardiac KE, and a measurement of the diameter and percentage collapse of the inferior vena cava (IVC) with echocardiography, to determine fluid status.

The study is finished when the patient is compensated and discharged from the hospital. This decision is made by the cardiologist at the cardiology ward. The amount of study related measurement will thus depend on the number of days admitted to the hospital.

Contactpersonen

Publiek

Maxima Medical Centre
Cyrille Herkert

+31645228805

Wetenschappelijk

Maxima Medical Centre
Cyrille Herkert

+31645228805

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients diagnosed with HFrEF, HFmrEF or HFpEF regardless of etiology
2. Presentation on the emergency department with ADHF
3. Age ≥ 16 years
4. Able to speak and read the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Atrial heart rhythm disturbances at presentation
2. Hemodynamic significant valvular disease
3. Pulmonary arterial hypertension due to other causes than a left sided heart problem
4. Receiving iv inotropic medication during hospital admission.

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 gestopt
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	15
Type:	Werkelijke 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	NL9133
Ander register	METC MMC (study received a waiver that ethical approval was not required) : N18.069

Resultaten

Samenvatting resultaten
N/A