Investigation of the Hemodynamic Cardiac Profiler in assessing cardiac indices and clinical performance during exercise and cardiac stress

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Reproducibility and validity of the new Hemodynamic Cardiac Profiler (HCP) device in rest and exercise in healthy volunteers will be ICC > 0.60.

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

Samenvatting

ID

NL-OMON23429

Bron
NTR

Verkorte titel
PROFILER study

Aandoening

stable ischemic heart disease

Ondersteuning

Primaire sponsor: Hemologic B.V.
Overige ondersteuning: Hemologic B.V..

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

two way random intraclass correlation coefficient and the associated 95% CI of the four measurements of change in stroke volume slope using the HCP during CPX in healthy volunteers and in patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Aim of this 3-phase study is to investigate the reproducibility and validity of the new Hemodynamic Cardiac Profiler (HCP) device in rest and exercise in healthy volunteers and in patients who succesfully completed cardiac rehabilitation and to investigate weather changes in SV as measured by HCP LVVTC are related to physical fitness.

Rationale: The assessment of hemodynamic indices is of interest to evaluate performance in athletes, changes in exercise capacity due to lifestyle interventions, and medical therapies in patients with ischemic heart disease. Current non-invasive options to measure cardiac output (CO) and stroke volume (SV) during exercise and cardiac stress include exercise-transthoracic echocardiography (X-TTE) and exercise-MRI. However, both these imaging modalities are expensive, highly complex, and are not readily available in all clinical settings. The Hemodynamic Cardiac Profiler device (HCP) has been shown to be reliably able to non-invasively track changes in left ventricular stroke volume in rest by producing left ventricle volume-time curves (LVVTC). However, the HCP has not been validated during exercise or cardiac stress. Furthermore, it is not known whether the measurements of HCP are related to other established (prognostic) measurements of cardiopulmonary fitness, such as cardiopulmonary exercise testing (CPX) (VO2peak and O2-pulse).
Objective: To investigate the reproducibility and validity of HCP in rest and exercise and to investigate whether changes in SV and CO as measured by HCP LVVTC are related to physical fitness.
Study design: The current study is a 3-phase, prospective reproducibility, validation and measurement pilot study.
Study population: Healthy volunteers > 18 years (phase 1 and 2), patients with stable ischemic heart disease and cardiac rehabilitation completed (phase 3).
Investigation: The HCP consists of 12 standard ECG-electrodes attached on the thorax in a pre-defined pattern, and uses low-intensity, patient-safe, high-frequent applied AC currents to measure LVVTCs.
Main study parameters/endpoints:
Phase 1: Intraclass correlation coefficient of the four measurements of changes in stroke volume slope using the HCP during CPX in healthy volunteers.
Phase 2: Intraclass correlation coefficient between the measurements of changes in stroke volume slope between the HCP and CPX and Pearson’s correlation coefficients between changes in stroke volume slope measured using the HCP and changes in O2-pulse and VO2max (CPX) in healthy volunteers.
Phase 3: Intraclass correlation coefficient between the measurements of changes in stroke volume slope between the HCP and CPX and Pearson’s correlation coefficients between

changes in stroke volume slope measured using the HCP and changes in O2-pulse and VO2max (CPX) in individuals with stable ischemic heart disease.

Doel van het onderzoek

Reproducibility and validity of the new Hemodynamic Cardiac Profiler (HCP) device in rest and exercise in healthy volunteers will be ICC > 0.60.

Onderzoeksopzet

phase 1,2,3

Contactpersonen

Publiek

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Wetenschappelijk

Amsterdam UMC - Location AMC
Harald Jorstad

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy volunteers aged 18 and older (phase 1,2) and stable ischemic heart disease patients and cardiac rehabilitation completed (phase 3)

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

symptomatic heart failure, inability or any contraindication to perform physical exercise, unstable ischemic heart disease, planned coronary revascularization, any significant valve pathology (grade >2), history of any open heart surgery, any chest malformation, any metal implants in the thoracic area

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-07-2017
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-07-2019
Soort:	Eerste indiening

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	NL7847
Ander register	METC AMC : METC2017_054

Resultaten