INVESTIGATION OF THE HEMODYNAMIC CARDIAC PROFILER IN ASSESSING CARDIAC INDICES AND CLINICAL PERFORMANCE DURING EXERCISE AND CARDIAC STRESS

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Primary Objective: Phase 1: Reproducibility To investigate the reproducibility of the LVVTCs of the HCP during exercise (cardiopulmonary exercise testing, CPX). Phase 2: Validation and association with physical fitness in healthy volunteers. To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48698

Source
ToetsingOnline

Brief title
Profiler study

Condition

- Other condition
- Heart failures

Synonym
cardiac failure, exercise intolerance

Health condition

slechte inspannings intolerantie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Hemologic

Intervention

Keyword: Cardiac indices, Exercise testing

Outcome measures

Primary outcome

Phase 1: Intraclass correlation coefficient between the four measurements of changes in stroke volume slope using the HCP during cardiopulmonary exercise testing (CPX).

Phase 2:

Intraclass correlation coefficient between the measurements of changes in stroke volume slope using the HCP during CPX and Pearson*s correlation coefficients between changes in stroke volume slope measured using the HCP and changes in O2pulse and VO2max (CPX) in healthy volunteers.

Phase 3:

Intraclass correlation coefficient between the measurements of changes in stroke volume slope using the HCP during CPX and Pearson*s correlation coefficients between changes in stroke volume slope measured using the HCP and changes in O2pulse and VO2max (CPX) in patients with stable ischemic heart

disease.

Additional MRI study:

Intraclass correlation coefficient between the measurements of stroke volume between the HCP and MRI per data point in the volume-time curve.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

- The association between E/A ratio as measured during exercise X-TTE with diastolic parameters derived from the HCP (Volume change during early filling phase / Volume change during late filling phase = Ev/Av)
- Resting and exercise echocardiographic parameters, in particular SV and CO as measured using VTI (additionally, LV/RF dimensions and function, valve function, LV diastolic function, VCI diameter, dp/dt) and its association with relevant HCP parameters.

MRI study

o The reproducibility of LVVTC produced by HCP.

o Stroke volume variations between HCP and MRI

Other study parameters (if applicable)

1. HCP parameters:

- Time of systole/ diastole (S/D-ratio = tSystole/tDiastole)
- Left-ventricular ejection time (LVET [ms])

2. V02peak (absolute, indexed for gender, age, body mass or lean body mass) and

O2pulse (and other relevant parameters, such as VE/VCO2 slope)

3. The association between self-reported physical activity

(SQUASH-questionnaire), VO2peak, and max levels of exercise (watts, METS,

duration).

4. Hb and Ht using finger prick

Study description

Background summary

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).

Study objective

Primary Objective:
Phase 1: Reproducibility
To investigate the reproducibility of the LVVTCs of the HCP during exercise (cardiopulmonary exercise testing, CPX).

Phase 2: Validation and association with physical fitness in healthy volunteers.
To validate the HCP LVVTC during exercise against SV as measured during CPX in healthy volunteers.
To investigate the association of the HCP LVVTC delta SV during exercise and parameters for cardiopulmonary fitness (CPX; VO2peak and O2-pulse) in healthy

volunteers.

Phase 3:
To validate the HCP LVVTC during exercise against SV as measured during CPX in patients with stable ischemic heart disease.
To investigate the association of the HCP LVVTC delta SV during exercise and parameters for cardiopulmonary fitness (CPX; VO2peak and O2-pulse) in patients with stable ischemic heart disease.

MRI Study:
To compare LVVTC parameters using HCP and MRI in healthy volunteers and in patients with stable ischemic disease and to compare LVVTCs obtained using HCP and MRI in healthy volunteers and in patients with stable ischemic disease.

Secondary Objectives:
- The reproducibility of LVVTC produced by HCP.
- Stroke volume variations in rest between HCP and MRI

Study design

The current study is a 3-phase, prospective reproducibility, validation and measurement study

Phase 1:
Reproducibility of LVVTC during exercise in healthy volunteers.

Phase 2:
- Validation of LVVTC delta SV as measured by CPX in healthy volunteers.
- Association between LVVTC and physical fitness, as measured by VO2peak and O2pulse (CPX) in healthy volunteers.

Phase 3:
- Validation of LVVTC delta SV as measured by CPX in individuals with stable ischemic heart disease.
- Association between LVVTC and physical fitness, as measured by VO2peak and O2pulse (CPX) in individuals with stable ischemic heart disease.

Between phases 2 and 3, an evaluation of phase 1 and 2 will take place. If reproducibility and validity have been established in healthy volunteers, phase 3 will be initiated in patients. If these parameters have not been established, evaluation will take place and problems preventing reproducibility and validity will, if possible, be inventoried. If possible, software or hardware modification of HCP will take place, and phase 1 will be re-initiated. If after phase three results show an extra recalibration of HCP LVVTC is necessary, a second MRI study with patients who are already included in phase 3 will be executed.

An additional MRI study will be initiated to apply a modification of HCP software and consequently establish a higher Intraclass correlation for reproducibility and validity.

This additional MRI study consist of:
Calibration of HCP LVVTC with MRI. A detailed analysis of the different parts of the LVVTC will be performed using established parameters, such as systolic and diastolic times and slopes of the curve.

Intervention

Phase 1a Reproducibility:

HCP during exercise (a total of 10 subjects)

4 conventional bike tests per subject
4 recumbent bike exercise tests per subject

Phase 1b Validity:(a total of 40 subjects)

Resting echo
During exercise:
1x HCP vs.
- Exercise echo
- Nexfin

Phase 2a Association with physical fitness in healthy volunteers (20 subjects)

During exercise:
HCP vs.
- Cardiopulmonary exercise test
- Nexfin

Resting:
- echo
- laboratory

2b Association with physical fitness in patients with ischemic heart disease (20 subjects)

During exercise:
HCP vs.
- Cardiopulmonary exercise test
- Nexfin

Resting:
- echo

- laboratory

Study burden and risks

There will be no benefits for the participants. For patients with ischemic heart disease the value in participating in the study will be that a new noninvasive device is tested and validated for exercise testing. Exercise testing is a standard clinical diagnostic procedure for this patient group. HCP profiler may aid in diagnostics and facilitate early detection of problems and may become a very useful addition to standard clinical tests. .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteers (phases 1 and 2, MRI study)
- >18 years of age
- Informed consent ,
Patients with stable ischemic heart disease (phase 3, MRI study)
- Informed consent
- > 18 years
- ischemic heart disease
- cardiac rehabilitation completed

Exclusion criteria

- symptomatic heart failure
- unstable ischemic heart disease
- planned coronary revascularization
- any significant valve pathology (grade >2)
- any right-sided structural pathology or reduced function (Tapse <1.5cm)
- inability or any contra-indication to perform physical exercise
- any metal implants in the thoracic area
- any chest malformation
- history of any open heart surgery

Exclusion criteria additional MRI study
- Pacemaker
- ICD
- Cocholear implant
- Implanted insulin pump
- Aneurysm clips implanted before 1990
- Weight over 140 kg.
- Possible metal splinter in eye
- Neurostimulator

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2017
Enrollment:	69
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL60812.018.17