Blood flow to leg muscles measured with phase-contrast MRI during supine exercise in patients with chronic heart failure.

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The aim of this project is (1) to examine reproducibility of measuring CO and LBF with PC-MRI during supine cycling (phase I) and (2) to measure CO and LBF during supine cycling in patients with CHF and healthy age-matched controls to investigate…

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

Summary

ID

NL-OMON43173

Source
ToetsingOnline

Brief title
MR-FLOW trial

Condition

- Heart failures

Synonym
Chronic heart failure, diminished pump-function of the heart.

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Afdeling FLOW van Máxima Medisch Centrum

Intervention

Keyword: Blood flow, Chronic heart failure, Distribution, phase-contrast MRI

Outcome measures

Primary outcome

Phase 1: Difference and agreement of blood flow (L/min) in the ascending (CO)

en distal aorta (LBF) measured with PC-MRI in rest en during submaximal

exercise between two days.

Phase 2: Difference of DF (ratio) between patients with CHF and healthy,

age-matched controls.

Secondary outcome

N.A.

Study description

Background summary

Patients with chronic heart failure (CHF) suffer from exercise intolerance. Several studies showed that reduced leg blood flow (LBF) to exercising muscles during daily activity is an important determinant of reduced exercise capacity. Theoretically, LBF is determined by two main factors: cardiac output (CO) and the distribution of blood to exercising muscles. It is evident that patients with CHF have a reduced cardiac output during exercise as compared to healthy subjects. In addition, the fraction of blood flow distributed to exercising muscles (distribution factor - DF) during exercise may be reduced due to an enhanced activity of the sympathic nervous system, changes in humoral factors, mechanical factors and inflammatory factors. To what extent the DF is causing the diminished LBF - and thereby is causing a reduced exercise capacity - is unknown.

Phase contrast MRI (PC-MRI) is a proven technique to measure blood flow in large arteries. Different studies also have shown that PC-MRI has the

capability of measuring blood flow in the aorta during exercise at different levels. However, these studies did only measure the inter-rater reliability and never measure the day-to-day reproducability.
If PC-MRI has the opportunity to reliable measure blood flow in the ascending and distal aorta (as a measurement of CO and LBF respectively) it would give a better understanding to what extent the CO and DF is responsible for the reduction of LBF. It would increase knowledge of the pathophysiology and consequently offers opportunities to tailor treatment and prevent unnecessary interventions. Therefore a technique to measure CO and LBF noninvasively could be a valuable tool in future clinical practice to individualize treatment.

Study objective

The aim of this project is (1) to examine reproducibility of measuring CO and LBF with PC-MRI during supine cycling (phase I) and (2) to measure CO and LBF during supine cycling in patients with CHF and healthy age-matched controls to investigate the relative contribution of cardiac function (CO) and impaired blood flow distribution (DF) in LBF (phase II).

Study design

prospective observational design without invasive measurements.

Study burden and risks

No adverse effects of symptom limited exercise testing performed by CHF patients or healthy controls have been reported in literature, nor in our clinical experience. With the inclusion of electrocardiographic analysis and blood pressure measurements during this exercise test, subjects with myocardial ischaemia and ventricular arrhythmias can be identified and excluded.
Also no adverse effects have been reported in literature for supine exercise testing which we will apply for MRI measurements. PC-MRI is a non-invasive measurement and places no additional burden on the subjects. Subjects with claustrophobia will be excluded at the start of the study.

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

Phase 1: Healthy volunteers in the age of 18-50 years that are able to perform maximal exercise test.
Phase 2: Patients with systolic heart failure (dilating or ischemic), NYHA-class II/III and ejection fraction <40%.

Exclusion criteria

Phase 1: Cardiovascular disease and Orthopaedic, pulmonary, neuromuscular and other diseases limiting exercise capacity. Claustrophobia.
Phase 2: Recent myocardial infarction (< 3 months), decompensated heart failure, ventricular tachycardia or myocardial ischemia during exercise.
Orthopaedic, vascular, pulmonary, neuromuscular and other disease
limiting exercise capacity in a way that performing exercise tests is not feasible.
Claustrophobia.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL59443.015.16
Other	VOLGT