Effects of High intensity Interval Training on CENTRAL hemodynamics at rest and during exercise

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Ethical review	Approved WMO
Status	Completed
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON37552

Source
ToetsingOnline

Brief title
HIT-CENTRAL

Condition

- Heart failures

Synonym
Chronic heart failure, left ventricular systolic dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: unrestricted grant Medtronic;wetenschapsfonds maxima medisch centrum

Intervention

Keyword: Cardiac output, Central hemodynamics, Chronic Heart Failure, Exercise training

Outcome measures

Primary outcome

Primary endpoints:

1. Training induced changes in resting cardiac output as determined by cMRI.

2. Correlation between training induced changes in resting cardiac output and

cardiac output during maximal exercise (LiDCO).

Secondary outcome

Secondary endpoints:

Correlation between training induced changes in resting c.q. exercizing

cardiac output and changes in the following variables:

* Cardiac size at rest (cMRI)

* Cardiac output onset and recovery kinetics at submaximal exercise (LiDCO)

* Recovery kinetics of muscle tissue oxygenation after submaximal exercise

(Near Infrared Spectroscopy)

* Quality of life (Minnesota Living With Heart Failure Questionnaire)

Study description

Background summary

Physical training has beneficial effects on exercise capacity, cardiac function, quality of life and mortality in patients with chronic heart failure (CHF). However, the optimal training mode and intensity are not yet established.
In a recent small trial in elderly CHF patients, high intensity interval training (HIT) was shown to be superior to moderate intensity exercise

training. Whereas both training modalities resulted in improved skeletal muscle metabolism and perfusion, HIT also induced improvements in cardiac function and size. However, as cardiac function was assessed at rest only, and measurements were performed by 2D echocardiography, which has limited accuracy for this purpose in patients with remodeled hearts, definitive conclusions cannot be drawn from this study.

Study objective

The main objectives of this study are to evaluate the effects of HIT in CHF patients on cardiac output at rest assessed with cardiac magnetic resonance imaging(cMRI), and to investigate the relation between changes in resting cardiac output and changes in cardiac output during maximal exercise (assessed by LiDCO). Secondary objectives are to investigate the relation between training-induced changes in central haemodynamics and changes in the following variables: cardiac size at rest, cardiac output kinetics during and after submaximal exercise, local oxygen delivery in skeletal muscles and quality of life

Study design

prospective randomised controlled intervention trial

Intervention

HIT is performed 3 times a week during 12 weeks and consists of 4 intervals of 4 minutes cycling on a ergometer at 85-95% of the peak aerobic capacity (peak Vo2) separated by 3 minute active pauses. The entire program is performed in the hospital under direct supervision of trained physiotherapists.

Study burden and risks

Exercise training performed by patients with chronic heart failure patients is considered to be safe and has a class Ia recommendation for treatment of CHF patients.
The HIT program that will be used in this study has been evaluated in a similar population of elderly CHF patients and also in patients with coronary artery disease without any documented harmful effects. In order to reduce potential risks of exercise training all patients perform a maximal cardiopulmonary exercise test at baseline, excluding patients with myocardial ischaemia and ventricular arrhythmias during exercise. Training sessions will be under supervision of trained physiotherapist in a clinical setting.
Regarding the study procedures:
Cardiac output during exercise is evaluated by using a method (LIDCO) requiring radial artery cannulation. Radial artery canulation is considered to be relatively safe with complication rate of 0.09% for permanent ischemia of the

hand. To ensure collateral circulation a normal Allen test must be present. Puncture will be under local anaesthesia to minimize patients burden. In patients who take oral anticoagulation , dosage will be temporarily adjusted (INR <1,5) for the safety of the procedure. Patients will be screened for contra indications before cardiac MRI.

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

* Written informed consent.
* Systolic heart failure due to ischemic cardiomyopathy (due to one or more myocardial infarction, as confirmed with echocardiography) or dilating cardiomyopathy (no history of myocardial infarction, no proven ischemia, no congenital heart disease en no severe valve

disorder)
* Left ventricular ejection fraction (LVEF) * 40% (assessed within 3 months before inclusion by echocardiography, MRI or radionuclear measurement)
* New York Heart Association (NYHA) class II or III
* Optimal medical treatment

Exclusion criteria

* Myocardial infarction or unstable angina less than 3 months prior to inclusion
* Clinical signs of decompensated heart failure
* Ventricular tachycardia or ischemia during exercise
* Participation in a training program (*2/week) in the last year
* Intracardiac shunts or congenital heart disease limiting exercise capacity
* Orthopaedic, vascular, pulmonary, neuromuscular and other disease limiting exercise capacity in a way that the training program is not feasible.
* Pathological Allen test , In casu no sufficient collateral circulation to the hand, in case of radial artery cannulation.
*MRI will not be part of the studyprotocol in eligible patients with pacemaker/ICD or other contra indications for MRI

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-11-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2011
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	01-02-2012
Application type:	Amendment
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

ID: 28867
Source: NTR
Title:

In other registers

Register	ID
Other	3041
CCMO	NL37770.015.11
OMON	NL-OMON28867