Effects of high intensity interval training on cardiac function at rest and during exercise.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28867

Source
Nationaal Trial Register

Brief title
HIT-CENTRAL

Health condition

Chronic heart failure
exercise intolerance
central hemodynamics

Sponsors and support

Primary sponsor: Maxima Medical Centre (board of directors)
Source(s) of monetary or material Support: self financing research

Intervention

Outcome measures

Primary outcome

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

Correlation between training induced changes in resting c.q. exercizing cardiac output and changes in the following variables:

1. Cardiac size at rest (cMRI);

2. Cardiac output onset and recovery kinetics at submaximal exercise (LiDCO);

3. Recovery kinetics of muscle tissue oxygenation after submaximal exercise (Near Infrared Spectroscopy).

Study description

Background summary

Rationale:

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.

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.

Study population:

Stable CHF patients (left ventricular ejection fraction ≤40%), NYHA class II or III, on optimal medical treatment, who are able and motivated to perform an exercise training program.

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.

Main study parameters/endpoints:

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 endpoints:

Correlation between training induced changes in resting c.q. exercizing cardiac output and changes in the following variables:

1. Cardiac size at rest (cMRI);

2. Cardiac output onset and recovery kinetics at submaximal exercise (LiDCO);

3. Recovery kinetics of muscle tissue oxygenation after submaximal exercise (Near Infrared Spectroscopy);

4. Quality of life (Minnesota Living With Heart Failure Questionnaire).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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. All other study procedures are non-invasive and considered to be safe in the selected patient population.

Study objective

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 has limited accuracy for this purpose in patients with remodeled hearts, definitive conclusions cannot be drawn from this study.

Study design

1. Baseline assesment;

2. Intervention 3 months fysiotherapy;

3. Final assesment.

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.

The control group receives global exercise advice, but no training by a physiotherapist. Controls can receive training once the trial has been finished.

Contacts

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Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. 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);

3. Left ventricular ejection fraction (LVEF) ≤ 40% (assessed within 3 months before inclusion by echocardiography, MRI or radionuclear measurement);

4. New York Heart Association (NYHA) class II or III;

5. Optimal medical treatment.

Exclusion criteria

1. Myocardial infarction or unstable angina less than 3 months prior to inclusion;

2. Clinical signs of decompensated heart failure;

3. Ventricular tachycardia or ischemia during exercise;

4. Participation in a training program (≥2/week) in the last year;

5. Intracardiac shunts or congenital heart disease limiting exercise capacity;

6. Orthopaedic, vascular, pulmonary, neuromuscular and other disease limiting exercise capacity in a way that the training program is not feasible;

7. Pathological Allen test, In case no sufficient collateral circulation to the hand, in case of radial artery cannulation;

8. General contra indication for MRI.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37552
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2895
NTR-old	NTR3041
CCMO	NL37770.015.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37552

Study results

Summary results
Kemps HM, Schep G, Zonderland ML et al. Are oxygen uptake kinetics in chronic heart failure limited by oxygen delivery or oxygen utilization? Int J Cardiol 2010;142:138-144.
Kemps HM, Prompers JJ, Wessels B et al. Skeletal muscle metabolic recovery following submaximal exercise in chronic heart failure is limited more by O(2) delivery than O(2) utilization. Clin Sci (Lond) 2010;118:203-210.