Train hard is smart for the heart.

No registrations found.

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

Summary

ID

NL-OMON23141

Source
NTR

Brief title
Train hard is smart for the heart

Health condition

Heart Failure
Cardiac Failure
Myocardial Failure
Congestive Heart Failure
Heart Decompensation

Sponsors and support

Primary sponsor: Radboud University Medical Centre
Source(s) of monetary or material Support: Radboud University Medical Centre

Intervention

Outcome measures

Primary outcome

1. Physcial fitness;

2. Brachial artery NO-dependent endothelium-dependent vasodilation;

3. Forearm resistance artery vascular bed NO-(in)dependent vasodilation;

4. Contribution of ET to the baseline forearm resistance artery vascular tone.

Secondary outcome

1. Cardiac structure and function;

2. Blood parameters that are (in)directly related to the progression and prognosis of HF;

3. Contribution of ET or NO to the exercise-induced vasodilation of the forearm vascular bed.

Study description

Background summary

Rationale:

In Western countries, heart failure (HF) is a major cause of death. Despite current advances in the pharmacological management of HF, the prevalence is rapidly increasing and the prognosis remains poor. Physical fitness is the single best predictor of both cardiac and all-cause deaths among patients with cardiovascular disease and outperforms ejection fraction as a prognostic index (for survival) in HF. Despite the overwhelming evidence to promote physical activity, little is known regarding the type of exercise that yields optimal beneficial effects in HF. Some studies in healthy subjects or those with cardiovascular risk suggest greater fitness and cardiovascular adaptations after high intensity exercise than with 'traditional' moderate exercise. The rationale is that high intensity exercise (i.e. short bouts of exercise at ~90% of the maximal heart rate) allows patients to complete work at higher workload/intensity, but for a short period of time, inducing beneficial peripheral adaptations in vessels and muscles, without overloading the heart. A sound comparison between the effects of 'traditional' moderate versus high intensity exercise training in HF patients has never been examined. Moreover, little is known about the underlying mechanisms that explain the beneficial effects of exercise in HF.

Objective:

This study aims to investigate the effects of 12 weeks of continuous versus interval exercise training versus a HF control group on physical fitness and cardiovascular health in heart failure patients. Furthermore the mechanisms of exercise-induced improvements in cardiovascular health will be investigated through vascular function measurements and assessments of changes on an genetic level.

Hypothesis:

We expect that continuous training will produce a moderate increase in physical fitness and accordingly a modest improvement in prognosis for heart failure patients. We expect that interval training will provide an optimal stimulus for peripheral improvements, leading to beneficial adaptations in vessels and muscles, but will also lead to an improvement in function and structure of the heart. Therefore, interval training will induce larger improvements in physical fitness and a larger improvement in prognosis for heart failure patients.

Study design:

Intervention study.

Study population;

84 heart failure patients.

Intervention:

Subjects will be randomly allocated to a 12-week intervention: 1. moderate-intensity exercise training, 2. high-intensity exercise training, or 3. control.

Main study parameters/endpoints:

1. Physical fitness (measured with a maximal cycling test);

2. NO-mediated endothelium-(in)dependent vasodilation of the forearm resistance arteries;

3. Contribution of ET to the baseline vascular tone of the forearm vascular bed.

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

The brachial catheterisation can induce a haematoma (~5%). However, this is completely reversible within 2 weeks and will not lead to permanent damage. Subjects will be informed regarding this potential risk associated with the invasive procedure of the test. During this

test, also blood will be taken for later analysis. Therefore, the number of invasive procedures will be minimised to 2.

The pharmaceutical drugs are all accepted for human use and will be infused in the forearm only (not in systemic doses), leading to a localised effect only. In addition, all substances will be removed by the body within minutes to hours (dependent on the substance). Moreover, >4,000 studies have previously used one or more of these substances to examine the local effects of endothelin and nitric oxide in the arms or legs of healthy humans as well as various patient groups (including heart failure). To the best of our knowledge, none of these previous studies reported the presence of (serious) adverse events.
Exercise training is not associated with a health risk. Moreover, exercise training typically causes a decreased cardiovascular risk, whilst vascular and cardiac function and structure improve after a period of exercise training. Also a number a previous studies have demonstrated that the cardiac workload during high intensity training is not significantly different to the (traditional)moderate-intensity training. Some studies have even demonstrated that the beneficial effects of exercise on remodelling of the heart are superior during high-intensity training compared with traditional moderate-intensity training in subjects with heart failure. Therefore, both types of exercise are not associated with an increased risk for development of health-related problems.

Study objective

We expect that the control group will show no increase or possibly even a decrease in physical fitness in the three-month period of the study. We expect that continuous training will produce a moderate increase in physical fitness however, we expect that interval training will induce the largest improvement in physical fitness in heart failure patients.

Study design

Zero weeks (baseline) and twelve weeks (post-intervention).

Intervention

1. 12 weeks of high-intensity interval exercise training, twice a week;

2. 12 weeks of moderate-intensity continuous exercise training, twice a week;

3. A control group who recieves usual care.

Contacts

Public
Phililps van Leijdenlaan 15
Nathalie M.M. Benda

Nijmegen 6525 EX
The Netherlands
+31 (024) 3614906
Scientific
Philips van Leijdenlaan 15
Nathalie M.M. Benda
Nijmegen 6525 EX
The Netherlands
+31 (024) 3614906

Eligibility criteria

Inclusion criteria

1. Heart failure NYHA classification II/III;

2. Ejection fraction < 45%;

3. Stable situation (clinically and pharmacological).

Exclusion criteria

1. Diabetes mellitus;

2. Hypercholesterolaemia;

3. Exercise-induced ischaemia;

4. Pre-menopausal females;

5. Pathology/disease that restricts patients from participation to exercise.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2011
Enrollment:	84
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-10-2012
Application type:	First submission

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
NTR-new	NL3495
NTR-old	NTR3671
Other	METC / ABR : 2010/065 / NL31612.091.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A