High Intensity Interval Training after Cardiac Resynchronization Therapy: a randomised controlled trial

Published: 18-11-2010
Last updated: 15-05-2024

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

Summary

ID

NL-OMON37928

Source
ToetsingOnline

Brief title
HIT-CRT

Condition

- Heart failures

Synonym
Cardiac Resynchronization Therapy, Chronic Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: stichting vrienden van het hart Zuidoost Brabant

Intervention

Keyword: Cardiac output, Cardiac resynchronization therapy, Exercise training, Heart failure

Outcome measures

Primary outcome

Changes in maximal exercise capacity are assessed by changes in peak VO2

Changes in cardiac output response to exercise before and after HIT

Secondary outcome

To investigate the additional effects of HIT after CRT on:

- Left ventricular function (left ventricular ejection fraction, end systolic

volume)

- Submaximal exercise capacity (rate of recovery of oxygen uptake after

submaximal exercise)

- Quality of life (Minnesota living with heart failure Questionnaire)

- Skeletal muscle tissue oxygenation

Study description

Background summary

Chronic heart failure (CHF) is an emerging problem in the Western World. In the last decade, it has been shown that implantation of a biventricular pacemaker/ICD, Cardiac Resynchronisation Therapy (CRT), can lead to a substantial improvement in cardiac function, and, as a consequence, in a reduction of morbidity and mortality in this patient category. In a preliminary trial it was shown that the effects of CRT on exercise capacity and quality of life can be improved even more by combining this therapy with exercise training. However, the optimal training intensity has not yet been established. In a recent trial in non-CRT heart failure patients, high intensity interval training (HIT) was shown to be superior to moderate intensity exercise training in terms of improving skeletal muscle metabolism, as well as cardiac function. Because the mechanisms of improvement in cardiac

function by CRT and HIT are presumably different, we hypothesize that HIT after CRT results in additive beneficial effects on exercise capacity through improvements in skeletal muscle metabolism and perfusion, as well as through an additional improvement in cardiac function (at rest and during exercise).

Study objective

The main objective of the study is to investigate whether HIT after CRT results in an additional increase in maximal exercise capacity. Secondary objectives are to investigate whether HIT yields additional improvements in submaximal exercise capacity, quality of life and left ventricular function. Another objective is to investigate the physiological background of the additional effects of HIT after CRT by measuring skeletal muscle tissue oxygenation (Near Infrared Spectroscopy) and cardiac output during exercise (radial artery pulse contour analysis method, LiDCO).

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 at 50-70% of peak Vo2. After each HIT sessions patients will perform muscle resistance training at moderate intensity. The entire program is supervised by trained physiotherapists

Study burden and risks

No adverse effects of exercise training performed by patients with a CRT device have been seen reported. Yet, exercise training was shown to result in an additional improvement in maximal exercise capacity, muscle strength and quality of life. The HIT program that will be used in this study has not been evaluated yet in patients that underwent CRT. However, it has been evaluated extensively in other populations, like elderly patients, non-CRT CHF patients and 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. Thresholds of the CRT device for anti tachycardia pacing or defibrillation will be set substantially above the maximal heart rate obtained at the maximal CPET. Training sessions will be under supervision of trained physiotherapist in a clinical setting
Cardiac output during exercise is evaluated by using a method requiring radial artery cannulation. This procedure 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. Cannulation 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

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 and no severe valve disorder)
-Left ventricular ejection fraction < 35% before CRT.

- New York Heart Association (NYHA) classII or III before CRT

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2010
Application type:	First submission

Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-05-2011
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-01-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-04-2012
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: 22642
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	2527
CCMO	NL33115.015.10
OMON	NL-OMON22642