High Intensity interval Training after Cardiac Resynchronization Therapy.

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In 2003 the number of chronic heart failure (CHF) patients in the Netherlands was estimated at 180.000. It is expected that ageing of the population in the Western world will dramatically increase this number in the near future. The management of...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22642

Bron
Nationaal Trial Register

Verkorte titel
HIT-CRT

Aandoening

Chronic Heart Failure
Cardiac Resynchronization Therapy
High Intensity Training

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Stichting Vrienden van het Hart Zuidoost Brabant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Changes in peak VO₂ after 3 months of HIT in CHF patients that underwent CRT as compared to a control group that received no training.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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 Resynchronization 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. Therefore, we hypothesize that this training modality may also be particularly beneficial in patients that underwent CRT.

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. Furthermore, we want to investigate the additional effect of HIT on NT-pro BNP, which is considered to be an important prognostic biomarker in CHF patients.

Study design:

Prospective randomised controlled intervention trial.

Study population:

Stable CHF patients (left ventricular ejection fraction <35%) who underwent CRT and 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 at 50-70% of peak VO2. After each HIT sessions patients will perform muscle resistance training at moderate intensity. The entire program is performed in the hospital under direct supervision of trained physiotherapists.

Main study parameters/endpoints:

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

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

No adverse effects of exercise training performed by patients with a CRT device have been reported in literature, nor in our clinical experience. Yet, exercise training was shown to have additional beneficial effects on 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, excluding patients with myocardial ischaemia and ventricular arrhythmias during exercise. 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.

Doel van het onderzoek

In 2003 the number of chronic heart failure (CHF) patients in the Netherlands was estimated at 180.000. It is expected that ageing of the population in the Western world will dramatically increase this number in the near future. The management of CHF currently includes both pharmacological and non-pharmacological interventions. Whereas pharmacological therapy improves survival in CHF patients4-8, the effects of these medications on exercise performance are less evident. This has led to an emerging interest in non-pharmacological adjunct therapies. In this respect, cardiac resynchronization therapy (CRT) was shown to be effective in improving exercise capacity and quality of life (QOL) in CHF patients. Recently, Patwala et al. demonstrated that exercise training following CRT leads to a further increase of these benefits. This study provided evidence that CRT alone improves cardiac function, while exercise training also enhances skeletal muscle function. The training program that was used

consisted of moderate intensity exercise. Yet, in a recent randomized controlled trial in non-CRT candidate heart failure patients, it was found that high intensity interval training (HIT) increased exercise capacity and QOL more than moderate training; HIT was not only associated with greater improvements in skeletal muscle metabolism and blood flow, but also with a marked reduction in left ventricular (LV) size and improvement in cardiac function (so called “reverse LV remodeling”). 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.

Onderzoeksopzet

All measurements as mentioned above will be performed at baseline, 3 months after implantation of teh CRT device and after completion of the 3 months during training program.

Onderzoeksproduct en/of interventie

Exercise training is performed 3 times as week during 12 weeks. Patients perform the training program at the department of physical therapy of their own hospital.
The HIT program is adapted from the study of Wisloff et al. in elderly CHF patients. It is performed on a bicycle ergometer with heart rate monitoring. Training commences with a 5 minute warming up period at 50-60% of peak VO2 achieved at the maximal exercise test which is performed after implantation of the CRT device. Subsequently, subjects perform 4 intervals of 4 minutes with a workload corresponding to 85-95% of peak VO2 achieved at the maximal CPET. The intervals are separated by 3 minute active pauses at 50-60% of peak VO2. After completion of the interval sessions there will be a 5 minute cool down, again at 50-60% of peak VO2.

After the HIT program, patients perform a resistance training program of moderate intensity, consisting of unilateral leg press, biceps curl, triceps extension and calf raise. 2 sets of 12 repetitions will be performed at 70% of 1-RM (the maximum achieved weight at one repetition).

Several precautions have been taken to minimize the risk of training. First, all subjects are trained in the hospital under direct supervision of trained physiotherapists. Second, all subjects perform a maximal exercise test at baseline; in this way, patients with ischemia or ventricular arrhythmias during high-intensity exercise can be excluded. Third, CRT devices with implantable defibrillator (ICD) will be programmed in a way that the zone for anti tachycardia pacing or defibrillation is at least 15 beats per minute below the individual maximal heart rate. Finally, all subjects will be asked to keep a diary, including weight, change in medication, any complaints and daily physical activities. In addition, the physiotherapist will be asked to note blood pressure and heart rate before and after training. Also they will be asked to note the 1-RM for strength training and Borg score for the interval training

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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) < 35% before CRT;

4. New York Heart Association (NYHA) class III before CRT.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37928
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2419
NTR-old	NTR2527
CCMO	NL33115.015.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37928

Resultaten

Samenvatting resultaten
Kemps HM, Schep G, De Vries WR et al. Predicting effects of exercise training in patients with heart failure secondary to ischemic or idiopathic dilated cardiomyopathy. Am J Cardiol 2008;102:1073-1078.

Kemps HM, De Vries WR, Hoogeveen AR, Zonderland ML, Thijssen EJ, Schep G. Reproducibility of onset and recovery oxygen uptake kinetics in moderately impaired patients with chronic heart failure. Eur J Appl Physiol 2007;100:45-52.

Kemps HM, Schep G, Hoogsteen J et al. Oxygen uptake kinetics in chronic heart failure: clinical and physiological aspects. Neth Heart J 2009;17:238-244.