Study of Myocardial Recovery after Exercise Training in Heart Failure

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The extent of beneficial effects of AIT, including reverse remodeling and improved left ventricular function, exercise capacity, quality of life and level of physical activity, needs to be established in a phase II type clinical multicenter study...

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON33053

Source
ToetsingOnline

Brief title
SMARTEX-HF study

Condition

- Heart failures

Synonym
decompensation, heartfailure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exercise training, heartfailure, Myocardial Recovery

Outcome measures

Primary outcome

Evaluation criteria are cardiac volumes and function, aerobic capacity, quality of life, and level of physical activity, assessed before and after the training program, and at follow-up one year after start of training.

Secondary outcome

Safety assesment of interval training in heartfailure.

To determine whether beneficial effects of training are sustainable for longer periods of time.

To assess whether AIT may reduce the incidence of serious adverse events, such as worsening of heart failure requiring intensified diuretic treatment, death or hospitalization due to cardiovascular disease within one year follow-up.

Study description

Background summary

This protocol describes a randomized multicenter clinical trial designed to test the hypothesis that a 12-week program of aerobic interval training (AIT) yields larger beneficial effects in stable heart failure patients than current practice, defined as either a similar training program with the same volume of moderate continuous training (MCT) or a recommendation of regular exercise at moderate intensity at individual choice (RRE). Evaluation criteria are left ventricular dimensions and function measured by echocardiography, aerobic capacity measured as peak oxygen uptake, quality of life, and the level of physical activity by questionnaires. Assessments will be made before and after the training program and at one year follow-up. Safety of AIT will be assessed as incidence of adverse effects during the training program. Clinical events will be recorded as worsening of heart failure requiring intensified drug

therapy (diuretics), ventricular arrhythmia, hospitalization due to cardiovascular disease, and all-cause mortality at one year follow-up.

Study objective

The extent of beneficial effects of AIT, including reverse remodeling and improved left ventricular function, exercise capacity, quality of life and level of physical activity, needs to be established in a phase II type clinical multicenter study with sufficient statistical power.
Safety of AIT during the supervised 12 week training program needs to be assessed.
Maintenance of beneficial effects beyond the supervised training period needs to be determined.
The incidence of clinical events like death, cardiovascular hospitalization, ventricular arrhythmia, and worsening of heart failure requiring intensified drug therapy (diuretics) needs to be estimated in order to indicate whether a phase III type clinical trial is warranted, and potentially for study size calculation.

Study design

The study will comprise all-cause heart failure patients, with coronary artery disease and dilated cardiomyopathy as main etiologies. Recruitment will be from outpatient heart failure management clinics and from patients referred to cardiac rehabilitation. All patients with LVEF <0.35 and NYHA class II-III will be assessed for eligibility and registered (see flow chart and Clinical Research Form, CFR). There will be no age limit, as most HF patients are elderly, but functional limitations of the ability to complete an exercise training program will be taken into consideration.

AIT group * Patients will warm up for 10 minutes at moderate intensity (corresponding to 50-60% of VO2peak, 60-70% of peak heart rate, 11-13 Borg scale, no shortness of breath) before walking/cycling four 4-minute intervals at high intensity (corresponding to 85-90% of VO2peak, 90-95% of peak heart rate, 15-17 Borg scale, shortness of breath). Each interval will be separated by 3-minutes active pauses, walking at 50-70% of peak heart rate. The training session will be terminated by 3-minutes cool-down at moderate intensity. Total exercise time will be 38 minutes for the AIT group. Special procedures for adjusting training intensity in patients with atrial fibrillation and patients carrying an ICD are described in the SOP.

MCT group * Patients will walk continuously at moderate intensity (as defined above) for 47 minutes each session to assure the training protocols are isocaloric (based upon previous studies21). All subjects will use a heart rate monitor to obtain the assigned exercise intensity. The Borg 6-20 scale will be used to measure the rate of perceived exertion during and after each training

session. The speed and inclination of the treadmill or the load on the bicycle ergometer will continuously be adjusted, to ensure that every training session will be carried out at the assigned heart rate throughout the 12-week training period.

The RRE group * Patients will be advised to exercise regularly in activities of their own preference. In addition they will meet for continuous treadmill walking of individual duration at 50-70% of peak heart rate for 20-30 minutes every three weeks, in order to motivate for post intervention testing. For safety, patients in the AIT and MCT patients will be checked briefly for signs of adverse effects by nurse or physician before training sessions every two weeks; for practical reasons RRE patients will be checked every three weeks.

Intervention

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Study burden and risks

Cardio-pulmonary exercise testing
Echocardiography
Quality of life questionnaire (KCCQ, HADS, GMS, Type D)
Level of Physical Activity (IPAQ questionnaire)
Registry adverse events
Holter
ICD interrogatie
60 ml blood at begin of the study

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

- congestive heart failure
- LVEF < 35%
- NYHA class II-III
- minimum 3 months of optimal medical treatment

Exclusion criteria

- significant intercurrent illness last 6 weeks
- known severe ventricular arrhythmia
- significant ischemia
- other heart disease that limits exercise tolerance

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	08-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	090309
CCMO	NL27991.041.09