The persisting effect of episodic exercise training in patients with chronic heart failure.

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Determine the prolonged effect of a 12 week physical exercise program in congestive heart failure patients.

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

Summary

ID

NL-OMON33578

Source
ToetsingOnline

Brief title
Exercise training in CHF patients/ PEP-HEART

Condition

- Heart failures

Synonym
Chronic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: exercise, heartfailure, inflammation

Outcome measures

Primary outcome

Improvement of the functional capacity and to determine the prolonged effects

of this intervention.

Secondary outcome

Secundairy endpoints are:

Serum levels of NT-proBNP

serum levels of CRP

Quality of live (assessed with MLHFQ)

Glycocalyx thickness measured with SDF.

Left ventricular ejection fraction

Study description

Background summary

Physical exercise has been shown to improve the functional capacity and the quality of life in patients with congestive heart failure. Currently it is unknown if physical exercise therapy has a prolonged beneficial effect in these patients. However, to implement physical exercise therapy as a treatment modality in the clinical care of congestive heart failure patients it is crucial to establish if there is a prolonged effect of this intervention. If so, exercise therapy would probably be feasible and cost-effective.

Study objective

Determine the prolonged effect of a 12 week physical exercise program in

congestive heart failure patients.

Study design

an open randomized prospective clinical trial.

Intervention

12 week physiotherapist guided exercise program

Study burden and risks

Patinets randomised to the exercise group will follow an intensive exercise program of 12 weeks, with 2 sessions a week for 90 minutes

Addiotional patients will visit the outpatient clinic of the OLVG for 4 times for the following investigations:

venapuncture
Quality of life assessment
physical examination
cardiac ultrasound
SDF measurement
Sic minute walking test

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

Inclusion criteria p 10
* Symptomatic systolic heart failure (documented clinical signs and symptoms of heart failure) documented for more than 3 months.
* Left ventricular ejection fraction (EF) less than 40% estimated by 2D echocardiography.
* New York Heart Association (NYHA) class: II and III.
* Age between 18- 80 years
* Clinically stable with regard to symptoms and optimal medical therapy for more than 2 weeks prior to inclusion.

Exclusion criteria

exclusion criteria p 11
* Orthopedic, peripheral vascular or neurological disease limiting the ability to exercise
* Documented exercise-induced ischemia
* Documented exercise-induced ventricular tachycardia
* Poorly controlled cardiac arrhythmias
* Significant chronic pulmonary disease limiting the ability to exercise
* Uncontrolled hypertension
* Abnormal blood pressure response to exercise testing (systolic blood pressure >250 mmHg or diastolic blood pressure >120 mmHg.) Or blood pressure drop of > 20mmHg during baseline exercise test.
* Major anemia
* Aortic valve stenose
* Co morbidity that contraindicate exercise
* Terminal disease
* Patients who can*t speak/understand or read the Dutch language

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	135
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	crestor
Generic name:	rosuvastatine
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	02-06-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2009-010476-22-NL
CCMO	NL21370.100.09