Exercise-related predictors of cardiac resynchronization therapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON40869

Source
ToetsingOnline

Brief title
'The EXERCISE trail'

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
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 Zuid-OostBrabant en firma Medtronic personele kosten)

Intervention

Keyword: exercise-echocardiography, heart failure, non-responder, resynchronization therapy

Outcome measures

Primary outcome

Correlation between exercise-related central hemodynamic and extra-cardiac parameters at baseline and the response to CRT, using logistic regression. Response to CRT is defined as a decline in end systolic left ventricular volume of at least 15% and/or increase of left ventricular ejection fraction (LVEF) of > 5%. Potential central hemodynamic predictors are assessed by exercise echocardiography (mitral regurgitation, LV volumes and intraventricular dyssynchrony) and radial artery pulse contour analysis (cardiac output). Potential extra cardiac predictors include peak oxygen uptake, oxygen uptake efficiency slope and kinetics of recovery of skeletal muscle oxygenation after sub maximal exercise using Near Infrared Spectroscopy.

Secondary outcome

None

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, i.e. Cardiac Resynchronisation Therapy (CRT), can lead to a substantial improvement of cardiac function, and, as a consequence, to reduction of morbidity and mortality in this patient category. However, when applying current selection criteria solely based on resting electrocardiography and functional status, appr. 40% of all CRT-candidates are non-responders; i.e.

do not show improvement of cardiac function or quality of life (QoL). Despite extensive research, the cause of non-response is not well understood. Previous trails unsuccessfully focussed on identification of echocardiographic parameters at rest as possible predictors of the response to CRT. However, other studies showed that hemodynamic parameters during exercise are superior for assessment of severity and prognosis of heart failure. We hypothesize, supported by several small trials, that central hemodynamic parameters during exercise are superior for predicting the response to CRT than resting parameters. Furthermore, extra-cardiac factors (e.g. skeletal muscle blood flow and metabolism) may also partly be responsible for non-response in certain patients. By combining exercise measurements of cardiac and skeletal muscle function during exercise, we believe it is possible to better characterise CHF patients and thus develop better models for the prediction of the effect of CRT.

Study objective

The primary objective of the study is to establish the predictive value of the combination of cardiac and extra-cardiac exercise parameters with respect to the response to CRT in CHF patients. Secondary objective is to improve insight in exercise-related physiological effects of CRT in these patients.

Study design

prospective observational cohort study

Study burden and risks

No adverse effects of cycle exercise testing performed by CHF patients, nor for supine exercise testing during echocardiography have been reported in literature.. Thresholds of the CRT device for anti tachycardia pacing or defibrillation will be set substantially (20 beats per minute) above the maximal heart rate obtained at maximal exercise testing. Testing sessions are supervised by an experienced physician.
Cardiac output during exercise is evaluated by using a method requiring radial artery cannulation. This procedure is considered relatively safe with a complication rate of 0.09% for permanent ischemia of the hand. To ensure collateral circulation a normal Allen test must be present. Puncture will be executed under local anaesthesia to minimize patient 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

heart failure NYHA class III
accepted for CRT, according to current guidelines
left ventricular ejection fraction < 35%

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
Intra cardiac shunts or congenital heart disease limiting exercise capacity
Orthopaedic, vascular, pulmonary, neuromuscular and other disease limiting exercise

capacity in a way that performing exercise tests is not feasible

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	06-10-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL49738.015.14