Feasibility and reproducibility of exercise echocardiography in patients with chronic heart failure

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* To establish the feasibility (i.e. % of measurements with sufficient quality for analysis) of exercise echocardiography in CHF patients, focusing on left ventricular function (LVEF), myocardial tissue motion (intra- and interventricular...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON38422

Source ToetsingOnline

Brief title Exercise echocardiography in CHF

Condition

• Heart failures

Synonym Chronic heart failure, left ventricular dysfunction

Research involving Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum Source(s) of monetary or material Support: Stichting Vrienden van het Hart

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Intervention

Keyword: Chronic heart failure, Echocardiography, Exercise

Outcome measures

Primary outcome

Feasibility (i.e. % of measurements with sufficient quality for analysis) of

the following exercise echocardiography variables:

- LVEF
- Intraventricular dyssynchrony (peak systolic longitudinal strain)
- Interventricular dyssynchrony (Inter Ventricular Mechanical Delay)
- Mitral regurgitation (regurgitant volume)

Day-to-day reproducibility of these exercise echocardiography variables (Blant

Altman analysis)

Secondary outcome

NA

Study description

Background summary

In recent years several studies have shown that exercise echocardiography has potentially added clinical value as compared to resting echocardiography as a tool for the evaluation of patient with chronic heart failure (CHF). Potential clinical applications that have arisen include grading of the severity of valvular disease (mitral regurgitation), assessment of prognosis, and prediction and assessment of the effects of cardiac resynchronization therapy in CHF patients. Currently, however, exercise echocardiography is poorly implemented in daily clinical practice.

Although several studies showed good intra- and interobserver variability of

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exercise echocardiography variables in selected populations of CHF patients, data on its feasibility are lacking. Moreover, no data exist on the reproducibility of potentially relevant exercise echocardiography variables such as left ventricular ejection fraction (LVEF), the severity of mitral regurgitation and myocardial tissue motion.

Study objective

* To establish the feasibility (i.e. % of measurements with sufficient quality for analysis) of exercise echocardiography in CHF patients, focusing on left ventricular function (LVEF), myocardial tissue motion (intra- and interventricular dyssynchrony) and the severity of mitral regurgitation.
* To determine the day-to-day reproducibility of these variables

Study design

The study is designed as a prospective observational study, including stable patients with stable CHF. Patients are requested to visit the hospitals 3 times. During the first visit patients undergo a routine clinical examination, followed by an incremental symptom limited exercise test with respiratory gas analysis . During the second and third visit (after 7 days and 9-14 days respectively) echocardiography is performed on an echocardiography stress table in a left lateral supine position. Measurements are performed at rest and subsequently during exercise using four 2-minute exercise bouts, respectively at 30%, 60% and 90% of the ventilatory threshold, and halfway between the ventilatory threshold and peak VO2. Images are stored for off line analysis by an experienced cardiologist blinded for the patient number and test order.

Study burden and risks

There are no direct benefits for individual participants other than additional information / insight into their disease based on the results of the exercise tests. On a population level, the results of this study may contribute to a wider implementation of exercise echocardiography which may improve the clinical assessment and therapy selection in CHF patients. No adverse effects of cycle exercise testing performed by CHF patients, nor for supine exercise testing during echocardiography have been reported in literature. Testing sessions are supervised by an experienced physician.

Contacts

Public Maxima Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Systolic heart failure due to ischemic cardiomyopathy or dilating cardiomyopathy
- Left ventricular ejection fraction * 40%

Exclusion criteria

- Myocardial infarction or unstable angina less than 3 months prior to inclusion

- Clinical signs of decompensated heart failure
- Documented 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

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2013
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO	
Date:	30-05-2013
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

ССМО

ID NL44300.015.13