

Acute effects of exercise in heart failure: A pilot study.

Gepubliceerd: 12-12-2012 Laatste bijgewerkt: 18-08-2022

Objective: The overall aim of this project is to investigate acute effects of moderate- and high-intensity exercise in heart failure patients and their age- and sex-matched controls on brachial artery shear patterns.

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

Samenvatting

ID

NL-OMON24144

Bron

Nationaal Trial Register

Aandoening

heart failure, exercise training, vascular shear rate
hartfalen, inspanning, training, bloedflow patronen

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre

Overige ondersteuning: Radboud University Nijmegen Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Oscillatory index;
2. Brachial artery blood flow patterns (antegrade and retrograde shear rate).

Diameter of the right brachial artery and velocity of the blood flow will be examined using the

non-invasive echo-Doppler. A 2-minute baseline recording will be acquired before starting the training session. A recording of the first ten minutes of the exercise session will be acquired continuously, while 1-minute ultrasound recordings are made every 5 minutes throughout the rest of the exercise session.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Heart failure is a syndrome characterized by variety of abnormalities, such as a low exercise tolerance, endothelial dysfunction and autonomic nerve dysfunction. Despite of improvements in pharmacological therapy, the prognosis in heart failure patients remains poor. Exercise training significantly improves symptoms and prognosis in heart failure. Recently, studies have demonstrated a potentially superior effect of high-intensity exercise training compared to traditional moderate-intensity training in heart failure. However, relatively little is known about the acute effects of such exercise bouts in heart failure. This is of special importance as these acute changes in physiological parameters (such as local shear stress) are regarded as the principle physiological stimulus for exercise-induced vascular adaptation. Differences in these responses between moderate-intensity training and high-intensity training may contribute to the different adaptations observed in heart failure.

An acute bout of exercise in healthy subjects induces systemic effects (such as increases in heart rate, stroke volume and peripheral resistance), as well as acute changes in conduit artery blood flow patterns and an increased shear stress. The latter is of special importance as shear patterns represents an important stimulus for exercise-induced vascular adaptations.

Brachial artery blood flow patterns during leg exercise have never been examined in heart failure patients. As heart failure patients demonstrate an enhanced baseline sympathetic activity and a disturbed thermoregulation, important regulators for the shear patterns, it can be hypothesized that the acute responses in brachial artery blood flow patterns, are different compared to healthy controls. Such knowledge is important to better understand the impact of exercise in heart failure. Currently little is known whether acute effects of high-intensity interval leg exercise and moderate-intensity continuous leg exercise on shear patterns differ.

Objective:

The overall aim of this project is to investigate acute effects of moderate- and high-intensity exercise in heart failure patients and their age- and sex-matched controls on brachial artery blood flow patterns (using echo-Doppler).

Study population:

15 patients diagnosed with heart failure and 15 healthy age- and sex-matched controls.

Main study parameters/endpoints:

1. Oscillatory index;
2. Brachial artery blood flow patterns (antegrade and retrograde shear rate) during leg exercise.

To provide a comprehensive insight we will also record secondary parameters that are (in)directly related to blood flow patterns. These parameters will be measured to explain potential differences we observe in our primary outcome parameter and include: heart rate variability to assess sympathetic and parasympathetic nerve activity, skin and core body temperature, heart rate and blood pressure.

Doel van het onderzoek

Objective: The overall aim of this project is to investigate acute effects of moderate- and high-intensity exercise in heart failure patients and their age- and sex-matched controls on brachial artery shear patterns.

Onderzoeksopzet

Brachial artery shear patterns, skin temperature and core body temperature will be measured at baseline and at several timepoints during exercise.

Heart rate variability will be measured at baseline, and 0, 30 and 60 minutes post-exercise.

Onderzoeksproduct en/of interventie

1. Moderate-intensity continuous exercise;
2. High-intensity interval exercise.

Maximal load and physical fitness level will be measured by the maximal wattage and peak oxygen uptake during an incremental cycling test (power will be increased with 10-20 W p/m), using a continuous gas analyzer. The data acquired during this test will be used to design a personal training program for each participant.

The moderate continuous training consists of cycling at 65% of maximal load (W) for 30 minutes. The high-intensity interval training consists of ten 1-minute intervals at 90% of maximal load, alternated by 2,5-minute periods of relative rest of cycling at 40% of maximal load. The warming-up (10min) and cooling-down (5min) are equal for both exercise sessions. Exercise sessions are designed to have identical duration and training loads.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patient group:

1. Patients diagnosed with heart failure NYHA class II/III;
2. ≥ 18 years of age;

3. Mentally able/allowed to give informed consent.

Control group:

1. Subjects free of cardiovascular disease and/or cardiovascular medication;
2. ≥ 18 years of age;
3. Mentally able/allowed to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contra-indications for exercise testing;
2. Pathology/disease that restricts patients from participation to exercise;
3. Serious co-morbidity.

For the use of the telemetric pill specific contra-indications are formulated.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2012

Aantal proefpersonen: 30
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 12-12-2012
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3589
NTR-old	NTR3755
Ander register	METC / CCMO : 2012/355 / NL 41067.091.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A