

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24144

### Source

Nationaal Trial Register

### Health condition

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

## Sponsors and support

**Primary sponsor:** Radboud University Nijmegen Medical Centre

**Source(s) of monetary or material Support:** Radboud University Nijmegen Medical Centre

## Intervention

## Outcome measures

### Primary outcome

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.

### **Secondary outcome**

1. Thermoregulatory changes (skin and core body temperature);
2. Autonomic function (heart rate variability).

## **Study description**

### **Background summary**

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.

### **Study objective**

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.

### **Study design**

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.

## **Intervention**

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.

## **Contacts**

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## **Eligibility criteria**

## Inclusion criteria

Patient group:

1. Patients diagnosed with heart failure NYHA class II/III;
2.  $\geq 18$  years of age;
3. Mentally able/allowed to give informed consent.

Control group:

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

## Exclusion criteria

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.

## Study design

### Design

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

Control: Active

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-12-2012

Enrollment: 30

Type: Anticipated

## Ethics review

Positive opinion

Date: 12-12-2012

Application type: First submission

## 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
NTR-new	NL3589
NTR-old	NTR3755
Other	METC / CCMO : 2012/355 / NL 41067.091.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Study results

## Summary results

N/A