# Is Plasma High Sensitive Cardiac Troponin I an Indicator of Cardiac Ischemic Injury after exercise test in healthy volunteers?

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Heart failures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34396

**Source**
ToetsingOnline

**Brief title**
Exercise test and cardiac injury

### Condition

- Heart failures

**Synonym**
Myocardial infarction

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** bicycle exercise test, remote ischemic preconditioning, Toll like receptors, Troponin I

## Outcome measures

### Primary outcome

high sensitive troponin I

### Secondary outcome

Ex-vivo stimulation of leucocytes from blood collected before and after the

RIPC-stimulus with measurement of cytokines (TNFα, IL6, IL10) in supernatant.

# Study description

### Background summary

Recent studies suggest that intensive exercise in healthy volunteers induces a rise in plasma troponin I as measured with a highly sensitive Elisa technique (hs-troponin I). This observation suggests that intensive exercise challenges the heart sufficiently to induce a mismatch in oxygen demand and supply resulting in mild cardiac injury. This opens a new window of opportunities to study interventions for their efficacy to modulate ischemia-reperfusion injury. To further characterize the rise in plasma hs-troponin I after intensive exercise, we will study the time course of troponin appearance in plasma. Furthermore, we will explore the effect of remote ischemic preconditioning (RIPC) on this plasma troponin appearance. RIPC is a proven tool to protect the heart against ischemia-reperfusion injury. Based on literature, we hypothesize that RIPC releases Toll Like Receptor (TLR) ligands from the remote organ that induces tolerance against subsequent exposure to TLR ligands.

### Study objective

The primary objective of the study is to explore the efficacy of intensive bicycle exercise test to induce cardiac micro-injuries by measurement of serum concentrations of hs-troponin I in healthy volunteers. The secondary objectives of this study are:

a)To investigate the cardioprotective effect of forearm RIPC during subsequent submaximal intensive bicycle exercise test;
b) To study if RIPC releases TLR agonists into the circulation which induce tolerance to subsequent TLR stimulation by using ex-vivo assays with circulating leucocytes and plasma that are collected before and after the RIPC protocol

## Study design

Single center, Pilot study

## Intervention

Remote ischemic preconditioning
(Sub)maximal bicycle exercise tests

## Study burden and risks

Since many years ago several types of exercise test (treadmill, bicycle) have been used for detecting ischemia in the patients suspected to ischemic cardiovascular diseases. Bicycle test is an alternative to treadmill testing .
It can also serve as a less expensive, portable substitute for testing. Bicycle exercise test can induce cardiac ischemia in healthy subjects and the patients with cardiovascular disease . However, the cardiac ischemia which developed following bicycle test is not harmful in healthy volunteers. Several previous studies have been shown the safety of RIPC protocol and no adverse effects have been reported in this regard. Therefore, it seems that bicycle exercise text and RIPC are two safe procedures with less probable adverse effect in healthy volunteers.
This pilot study will provide a feasible model to elucidate valuable unknown points regarding the mechanism of RIPC in prevention of reperfusion-ischemia which will be extremely helpful for the further studies.
Potential risks of bicycle exercise test could be considered in very rare cases as:
Acute coronary syndromes, acute respiratory events and sudden cardiac death. Sudden cardiac death is rare in apparently healthy individuals60. In individuals under the age of 40 years, sudden cardiac death is usually attributed to congenital heart disease, whereas CAD is a more likely cause for those over age 40. In our individuals these attributed risk factors will be assessed by pre-assessments.
The incidence of major cardiovascular complications during outpatient cardiac exercise programs has been estimated to be 1 in 60 000 participant hours.
Musculoskeletal Injuries: include direct injuries such as bruises, sprains, and strains, and indirect problems such as arthritis and back pain. Musculoskeletal Injuries could be prevented by sufficient education of the individuals before

the bicycle tests.

# 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

• Age : 18-45 years
• Willing to sign informed consent
• Healthy

## Exclusion criteria

• Hypertension

• Any cardiovascular abnormality in past medical history, physical examination or ECG.
• Drug abuse
• Alcohol abuse (> 3 units/day)
• Smoking
• BMI>=30 kg/m2
• Inability to perform bicycle exercise
• One or more of the items of the questionnaire (American Heart Association 12-point screening for exercise test) scores positive (see appendix of protocol)
• Any signs and symptoms of current infection based on physical examination and medical history
• Medical history of chronic infection or autoimmune diseases
• History of vaccine injection in recent 1 month.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-12-2010 |
| Enrollment: | 40 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 16-12-2010 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL34130.091.10 |