The effect of Remote Ischemic Preconditioning on plasma troponin I appearance after a standardized cycling test in healthy volunteers

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The primary objectives of the study is to test the hypothesis that in healthy volunteers RIPC (bilateral forearm ischemia and reperfusion) reduces troponin I appearance in plasma in response to a high intensive bicycle exercise test.

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON35150

Source
ToetsingOnline

Brief title
Exercise test and cardiac injury

Condition

- Myocardial disorders

Synonym
Cardiac injury

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: Exercise test, Remote Ischemic Preconditioning, Troponin I

Outcome measures

Primary outcome

Serum levels of hs-troponin I in response to intensive exercise test.

Secondary outcome

Not applicable

Study description

Background summary

We recently confirmed that a standardized, moderately intensive exercise (70 minutes of cycling at 80% of maximal heart rate reserve) in healthy volunteers induces a rise in plasma troponin I as measured with a highly sensitive Elisa technique (hs-troponin I; CMO 2010/337). This observation suggests that intensive exercise challenges the heart sufficiently to induce a mismatch in oxygen demand and supply resulting in an increase in cardiac troponins, potentially relating to mild cardiac injury. This opens a new window of opportunities to study interventions for their efficacy to modulate ischemia-reperfusion injury. However, the increase was only small and remote ischemic preconditioning (RIPC) did not affect this small increase significantly (n=12). Two of these volunteers with the largest increase in troponin I showed a marked effect of RIPC, reflected by an attenuation of the exercise-induced increase in troponin I. We hypothesize that the lack of effect of RIPC is explained by the limited cardiac stress of the exercise protocol used. Therefore, we propose now to study the effect of a more intense exercise test on plasma troponin I. Furthermore, we intensify the RIPC stimulus to further exclude an inadequate RIPC stimulus as a potential explanation for our negative finding.

Study objective

The primary objectives of the study is to test the hypothesis that in healthy volunteers RIPC (bilateral forearm ischemia and reperfusion) reduces troponin I appearance in plasma in response to a high intensive bicycle exercise test.

Study design

Single centre, randomized cross-over trial

Intervention

Maximal bicycle test (to determine maximal heart rate), at least one week later followed by two intensive bicycle exercise tests per volunteer, separated by at least 2 weeks. One of these intensive exercise tests will be preceded by forearm ischemia (three 5-min cycles of bilateral forearm ischaemia, induced by cuffs placed on both upper arms and simultaneously inflated to 200 mm Hg, followed by 5 min of reperfusion.

Study burden and risks

Submaximal bicycle exercise tests are safe in healthy volunteers without hypertension, normal ECG and without signs of cardiovascular disease. In a previous study (CMO 2010/337), 70 minutes of cycling exercise at 80% of maximal heart rate reserve appeared to be safe in a similarly selected group of healthy young individuals. The RIPC protocol that will be used in this study is safe, based on results from our own studies and observations by other research groups. This study will provide important data on the feasibility of high intensive bicycle exercise and subsequent measurement of plasma troponin as a tool to study cardiac ischemia-reperfusion injury in vivo.

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 (systolic blood pressure > 140 mmHg or diastolic blood pressure > 90 mmHg)
• Any cardiovascular abnormality in past medical history, physical examination or ECG, including prolonged QTc interval.
• Drug abuse
• Alcohol abuse (> 3 units/day)
• Smoking during the last 2 years
• BMI>=30 kg/m2
• Inability to perform bicycle exercise
• The presence of an absolute or relative contra-indication for exercise testing (table 2)
• The presence of diabetes (fasting glucose > 6.9 mmol/l, non-fasting glucose > 11.0 mmol/l; if non-fasting glucose is > 6.9 mmol/l, blood glucose measurement will be repeated in fasting condition and should then not exceed 6.9 mmol/l.)
• Total cholesterol in blood 6.5 mmol/l or higher

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-08-2011
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	NL37510.091.11