

Influence of remote ischemic preconditioning on cardiac function after endurance exercise

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To examine the effect of remote ischemic preconditioning on exercise-induced cTn elevations and indices of cardiac function.

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

Summary

ID

NL-OMON39515

Source

ToetsingOnline

Brief title

Ischemic preconditioning in endurance athletes

Condition

- Myocardial disorders

Synonym

acute myocardial infarction, athlete's heart

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

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

Intervention

Keyword: Cardiac function, Cardiac troponins, Endurance exercise, Remote ischemic preconditioning

Outcome measures

Primary outcome

Serum concentration of cardiac troponins (T and I) at baseline, pre-exercise and 0, 2, 4, 6, 8, 10 hours post-exercise. Indices of cardiac function measured at baseline and immediately post-exercise.

Secondary outcome

Other cardiac markers: e.g. NT-proBNP

Various molecular forms of cardiac troponin T and I

Markers to correct variation in renal function during exercise: e.g. creatinin, cystatin C, albumin, hematocrit.

Inflammatory markers: e.g. CRP

Oxidative status: e.g. thiobarbituric acid reactive substances (TBARS), trolox equivalent anti-oxidant capacity (TEAC), erythrocyte susceptibility to in vitro peroxidation.

Heart rate

Duration of 30km-run

Baseline blood pressure

Study description

Background summary

Increased levels of cardiac troponins (cTn) are the biochemical gold standard

to diagnose acute myocardial infarction (AMI). However, release of cTn into the circulation is not restricted to AMI, as cTn elevations are also frequently observed in athletes during and after endurance exercise. Since it is well-accepted that regular exercise training is part of a healthy lifestyle, it seems counterintuitive to ascribe exercise-induced cTn elevations to cardiac necrosis that characterizes AMI. Several clinical studies challenge the traditional interpretation of cTn as a *threshold* effect; and propose that cTn release is rather a physiological continuum from ischemia to infarction. Due to the rapid rise and fall of cTn in the first hours after exercise, as well as the possible presence of a cytosolic unbound cTn fraction in the cardiomyocyte (estimated 5% to 8%), exercise-induced cTn release may be consistent with the release of the cytosolic cTn pool (reversible damage) rather than the breakdown of the contractile apparatus (irreversible damage). The hypothesis of reversible cell damage is supported by the absence of late gadolinium enhancement on cardiac MRI in endurance athletes, a measurement for cardiac fibrosis.

Besides biochemical changes observed after endurance-type exercise, acute impairment in cardiac function has been observed as well. While early studies showed that intense endurance exercise causes acute left ventricular dysfunction, recent studies demonstrate an acute temporary alteration in right ventricular function. This right ventricular impairment is, in contrast to the left ventricle, strongly associated with post-exercise cTn concentrations. This suggests that right ventricular functional impairment and biochemical cardiac alterations seen after endurance exercise may be causally related.

Remote ischemic preconditioning (RIPC) represents a unique technique to gain more insight into the role of ischemia in exercise-induced functional and biochemical cardiac changes. RIPC is a non-invasive therapeutic intervention in which brief ischemia of one tissue or organ protects remote organs from an extended episode of ischemia-reperfusion. RIPC describes the practice of applying short cycles of 5 min ischemia in the arm, followed by 5 min reperfusion and has been shown to provide systemic protection during subsequent ischemic events. Thus far, RIPC has been shown to reduce cardiac damage in adults undergoing cardiac and vascular surgery.

Our working hypothesis is that functional and biochemical cardiac alterations seen after endurance exercise are caused by an oxygen demand-supply imbalance, which can be reduced by ischemic preconditioning. Therefore, this study aims to investigate the effect of RIPC (by applying short cycles of ischemia and reperfusion induced by a blood pressure cuff) on cTn elevations and temporary alterations in right ventricular function induced by a 30 km run in healthy trained long distance runners.

Study objective

To examine the effect of remote ischemic preconditioning on exercise-induced

cTn elevations and indices of cardiac function.

Study design

Single blind, cross-over study

Intervention

Remote ischemic preconditioning, induced by four 5 min cycles of upper limb ischemia interspaced with 5 min of reperfusion (200 mm Hg) or a control procedure with low-pressure cuff inflation (10 mm Hg), one hour before a 30 km run.

Study burden and risks

The risks involved in participating in this study are minimal. Minor discomfort may occur during the remote ischemic preconditioning protocol, but this intervention has been shown to be safe. Furthermore, repeated blood draws will be taken, with small local haematoma as only possible risk. In addition, participants will undergo three echocardiograms, which is a safe, non-invasive imaging technique. Since all participants will be experienced and well-trained long distance runners, no harmful effects are expected to occur during or after the 30 km run.

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

Informed consent

Healthy

Age between 18 and 65 years

Endurance-trained (two or more training sessions per week)

Exclusion criteria

Not applicable

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2013

Enrollment: 35
Type: Actual

Medical products/devices used

Generic name: Manual blood pressure cuff
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 27-06-2012
Application type: First submission
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO
Date: 28-03-2013
Application type: Amendment
Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL40687.068.12

Study results

Date completed: 30-06-2013

Actual enrolment: 29

Summary results

Trial is ongoing in other countries