Effect of ischemic postconditioning on targeting of Annexin A5 after forearm exercise

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1. To adjust and validate our forearm model for ischemia reperfusion injury, in order to used it for assessment of ischemic postconditioning.To adjust our forearm model for ischemia reperfusion injury, in order to used it for assessment of ischemia...

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

Summary

ID

NL-OMON30297

Source
ToetsingOnline

Brief title
IPost

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
ischemic reperfusion injury, 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,ZonMW

Intervention

Keyword: Annexin A5 targetting, health volunteers, ischemic reperfusion injury, postconditioning

Outcome measures

Primary outcome

Percentage difference in radioactivity (counts/pixel) between experimental and

control thenar muscle at 60 and 240 minutes after reperfusion.

Secondary outcome

Workload during (ischemic) exercise.

Study description

Background summary

Recently, ischemic postconditioning has been identified as a protective intervention against ischemia-reperfusion injury. In animal studies, the signalling pathway of this (impressive) protective phenomenon is very similar to ischemic preconditioning. It opens a new avenue of post-reperfusion interventions with drugs that have been shown to mimic ischemic preconditioning. Before we can study this phenomenon in our forearm ischemia-reperfusion model, we need additional validating experiments. The purpose of this study proposal is to provide these data.

Study objective

1. To adjust and validate our forearm model for ischemia reperfusion injury, in order to used it for assessment of ischemic postconditioning.

To adjust our forearm model for ischemia reperfusion injury, in order to used it for assessment of ischemia reperfusion damage in elderly and patients.

2. To test the effect of ischemic postconditioning on ischemia reperfusion injury in healthy volunteers, using Annexin binding after repetitive handgripping.

Study design

cross over design

Intervention

Study 1
ischemic exercise vs non-ischemic exercise of the non dominant forearm

Study 2:
10 minute delay between ischemic (exercise) and administration of Annexin A5 and intermittent reperfusion (1 minute reperfusion, 1 minute ischemia, during 8 minutes)

Study burden and risks

This study will be executed at the Clinical Research Centre Nijmegen under close medical supervision. All medical personnel at the research centre has been trained in basic life support, including the use of an assisted electric defibrillator (AED), which is available at the research centre.

Administration of radiolabeled annexin A5 results in an effective dose of less than 5 mSv, well within the range of accepted exposure to radioactivity for human research. Participation in this research does not interfere with possible diagnostic or therapeutic procedures with X-rays of radioactivity in the future.
Occurrence of an allergic reaction is theoretically possible upon administration of Annexin A5, however there have been no allergic reaction reported in all volunteers exposed to Annexin A5.
The volunteers will not benefit directly from participating in this study.

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

-Male
-Age 18-50 years
-No physical limitation to perform ischemic exercise
-Informed consent

Exclusion criteria

-Diabetes (fasting glucose >7,0mmol/l, or random glucose >11,0mmol/l)
-hyperlipidemia (fasting total cholesterol > 5.5 mmol/l)
-Hypertension (supine SBP/DBP > 140/90 mmHg at screening)
-Any cardiovascular disease
-Drug abuse
-Concomittant chronic use of medication
-Administration of radioactivity in research setting during the last 5 years
-Participation to any drug-investigation during the previous month as checked with VIP check according to CRCN standard procedures.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

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	NL15448.091.06