A study on organ protection during bypass sugery by inflating a bloodpressure cuff on the arm.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21859

Source
NTR

Brief title
RIPC-CABG

Health condition

CABG, remote preconditioning, cardioprotection

Sponsors and support

Primary sponsor: Academical Medical Centre, University of Amsterdam
Source(s) of monetary or material Support: Academical Medical Centre, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Differences in phosphorylation of PKC-e, p38MAKP, ERK and HSP27, before and after remote preconditioing, as compared to control.

Secondary outcome

N/A

Study description

Background summary

The aim of this clinical study is to investigate whether remote ischemic preconditioning induces a phosphorylation of signalling pathway molecules, such as PKC-e, p38MAPK, ERK and HSP27, in human myocardium.

Study objective

Recent clinical data showed that remote ischemic preconditioning attenuates myocardial damage during cardiac surgery. Classic preconditioning is abolished in diabetic patients. We will investigate the molecular effects of remote ischemic preconditioning on the myocardium, in both diabetics and non-diabetics.

Study design

Two myocardial biopsies will be obtained, the first after sternotomy and the second 30 minutes later, but prior to cardiopulmonary bypass.

Intervention

Remote ischemic preconditioning: By inflating a automateic inflator cuff around the upper arm, we will induce forearm ischemia for 5 minutes, followed by 5 minutes of reperfusion. This cylce will be repeated 2 times.

In the control group the cuff will be placed on the upper arm, but no inflating will be done.

Contacts

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Eligibility criteria

Inclusion criteria

1. CABG surgery with or without valve surgery;

2. Informed consent;

3. Age >18 years.

Exclusion criteria

1. Emergency surgery;

2. Heart failure;

3. Serious pulmonary disease;

4. Kidney failure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated): 28-07-2009

Enrollment: 56

Type: Anticipated

Ethics review

Positive opinion
Date: 27-07-2009

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	NL1821
NTR-old	NTR1931
Other	Medical Ethical Committee, AMC, University of Amsterdam : MEC 09/008
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A