

# A clinical study to investigate the molecular effects of remote ischemic preconditioning in the myocardium of CABG patients with or without diabetes mellitus

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33897

### Source

ToetsingOnline

### Brief title

RIPC-CABG

### Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

### Synonym

coronary artery bypass grafting

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** CABG, diabetes mellitus, remote ischemic preconditioning

## Outcome measures

### Primary outcome

Main study parameters are expression of signalling pathway proteins, detected by molecular analysis from myocardial probes taken before and after RIPC protocols during CABG surgery. ( PKC-\*, p38MAPK, ERK and HSP27).

### Secondary outcome

Ee will investigate standard hemodynamic parameters obtained during standard cardiac surgery.

## Study description

### Background summary

Recent clinical data showed that remote ischemic preconditioning (RIPC) attenuates myocardial damage in cardiac surgery. Although the exact mechanism of remote ischemic preconditioning, as well as classical preconditioning, is not clear, several pathways have been demonstrated to play a role transducing cardioprotection. Among others, mitogen activated kinase pathway (MAPK) has been shown to be involved. Supported by the evidence that remote ischemic preconditioning is able to precondition human myocardium, we hypothesize that this protection is mediated by regulation of expression of PKC-\*, p38MAPK, ERK and HSP27. We want to investigate this by molecular analysis of the preconditioned myocardium in CABG patients

### Study objective

The aim of this clinical study is to investigate whether remote ischemic preconditioning induces an activation or phosphorylation of signalling pathway

molecules (MAPK) in myocardium in patients undergoing coronary artery bypass graft (CABG) surgery.

## **Study design**

Single center, randomized, patient and investigator blinded, prospective study

## **Intervention**

The remote ischemic preconditioning protocol (RIPC) exist of 3\* 5 minutes of limb ischemia, induced by blood pressure cuff inflation of the upper arm. The first group will undergo this regimen after induction of anesthesia, but before start of the cardiopulmonary bypass to investigate molecular effects of preconditioning (RIPC). A second group, without remote ischemia, will serve as control group. Two additional groups with the same protocol will be performed in patients with diabetes mellitus.

## **Study burden and risks**

Patients will receive total intravenous anesthesia according to standard anaesthetic procedures. The patients in the groups preconditioning will receive 3x5min ischemia of the non dominant upper arm followed by reperfusion. This protocol has recently been tested in several clinical studies and has no known side effects. Because of anesthesia no discomfort is to be expected. Myocardial tissue samples will be obtained during placement of CPB, and no extra tissue will be taken.

## **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

>18 years, elective CABG surgery (with or without aortic valve surgery), written informed consent.

### Exclusion criteria

<18 years, emergency operations, pregnancy, severe COPD, absent informed consent, SaO<sub>2</sub><90% at room temperature, presumed non-cooperatives, legal incapacity, renal failure, liver failure

## Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-04-2009
Enrollment:	56
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL22522.018.08