# A clinical study on the effect of Remote Ischemic Conditioning on atrial fibrillation and Outcome after coronary artery bypass grafting (RICO-trial)

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

## Summary

### ID

NL-OMON33030

**Source**
ToetsingOnline

**Brief title**
RICO-trial

### Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**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:** atrial fibrillation, coronary artery bypass grafting surgery, remote ischemic postconditioning, remote ischemic preconditioning

## Outcome measures

### Primary outcome

The primary endpoint will be the incidence of atrial fibrillation in the first

72 hours after surgery in each of the intervention groups as compared to

control.

### Secondary outcome

Secondary endpoints will be the length of stay on the ICU and in the hospital,

the incidence of major cardiovascular events including death, rhythm

dissorders, heart failure, revascularisation, myocardial infarction, acute

coronary syndrome and stroke or transient ischemic attack after 30 days, 3

months and 1 year, in the intervention groups as compared to control.

# Study description

### Background summary

Recent clinical data showed that remote ischemic preconditioning protects the myocardium against ischemia reperfusion damage in coronary artery bypass grafting surgery (CABG). In animal experiments, also remote ischemic postconditioning reduced infarct size. Atrial fibrillation is a common adverse event after CABG and at least in part caused by ischemia reperfusion damage. Atrial fibrillation is associated with worse outcome. We hypothesize that remote ischemic pre- and postconditioning protects the heart against ischemia-reperfusion damage and thereby reduces the incidence of atrial

fibrillation after CABG.

### Study objective

The objective of this trial is to investigate whether remote ischemic preconditioning or remote ischemic postconditioning improves clinical outcome after coronary artery bypass grafting surgery, as measured by the incidence of postoperative atrial fibrillation, the length of stay on the ICU and in-hospital and the occurrence of major cardiovascular events at follow up.

### Study design

A prospective patient and investigator blinded randomized controlled multinational multicenter trial.

### Intervention

Remote ischemic conditioning, consisting of 3 cycles of 5 minutes upper arm ischemia followed by 5 minutes of reperfusion. One group will receive the conditioning stimulus before aortic cross clamping (RIPC), a second group during aortic cross clamping (Remote Post), a third group both before and during aortic crossclamping (Pre/Post) and the fourth group will be the control group, receiving no intervention.

### Study burden and risks

All patients will follow the surgical and anaesthetic procedures as standard in the respective hospital. In addition, the RIPC-, Remote Post- and Pre/Post-group will receive a remote ischemic conditioning stimulus, which is a safe intervention. Detection of postoperative atrial fibrillation will be done using Holter-devices for 72 hours. Patients will be contacted to evaluate the occurrence of major cardiovascular and cerebrovascular events at 30 days, 3 months and 1 year after surgery.

## 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

Elective CABG surgery using extra corporeal circulation
Written informed consent

## Exclusion criteria

Prior cardiac surgery (Re-operations)
Prior atrial fibrillation
Use of class 1 or 3 anti arrhythmic medication or digoxin
Use of intermittent aortic cross clamping during surgery
Age <18 years
Left ventricular ejection fraction *30%
Serious pulmonary disease (resting pO2 <90% at room air)
Renal failure (clearance <30 ml/min as calculated using the Modification of Diet in Renal Disease formula).
Liver failure
Use of the sulfonylurea derivative glibenclamide (this drug is known to block any preconditioning stimulus)

# Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2010 |
| Enrollment: | 300 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| 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 | NL28041.018.09 |