# Organ protection by noble gases * A clinical study to investigate Helium induced Pre- and Postconditioning in patients undergoing coronary artery bypass surgery.

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The aim of this clinical study is to investigate whether the non-anaesthetic noble gas helium induces preconditioning (PreC) and postconditioning (PostC) in patients undergoing coronary artery bypass graft (CABG) surgery

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

## Summary

### ID

NL-OMON31964

**Source**
ToetsingOnline

**Brief title**
Helium induced pre- and postconditioning in CABG patients. (HIPP-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, Helium, Postconditioning, Preconditioning

## Outcome measures

### Primary outcome

Main study parameters are detection of signalling pathway molecules involved in anaesthetic preconditioning (PKC-e, p38MAPK, ERK and HSP27). This will be done by molecular analysis of myocardial tissue samples in our laboratory.

### Secondary outcome

Secondary parameters are cardiac enzyme release after surgery (troponine T, CPK, CK-MB) and haemodynamics during surgery measured by transoesophageal echocardiography (TEE). Furthermore, several biomarkers will be investigated to see whether helium has a protective effect against surgery induced tissue damage in other organs; urine N-acetyl-glucosaminase (NAG) to estimate kidney damage, Intestinal-type fatty acid binding protein (I-FABP)/liver-type fatty acid binding protein (L-FABP)/ heart-type fatty acid binding protein (H-FABP) to estimate intestinal injury, and *-glutathione S-transferase (*-GST) to estimate liver damage

# Study description

### Background summary

Recent experimental and clinical data showed that the noble gas helium protects

against myocardial reperfusion injury in rabbits in vivo and induces late preconditioning in rat hearts. It has also been demonstrated that another noble gas, xenon, can protect from myocardial damage by postconditioning. Supported by this evidence we hypothesize that helium induces pre- and postconditioning in humans.

## Study objective

The aim of this clinical study is to investigate whether the non-anaesthetic noble gas helium induces preconditioning (PreC) and postconditioning (PostC) in patients undergoing coronary artery bypass graft (CABG) surgery

## Study design

single-center, randomized, investigator blinded prospective study. Administering Helium as preconditioning or postconditioning treatment. One group of patients will receive 3 * 5 minutes of Helium just before aortic cross clamping (preconditioning, PreC, group 2), another group will receive helium 3*5 min just before release of the aortic cross clamp (Postconditioning, PostC, group 3) and an additional group will receive both regimens (pre and postconditioning, PrePostC, group 4). One group of patients will serve as untreated controls (CON, group 1), and a positive control group will receive preconditioning with sevoflurane (3 * 5min) before aortic cross clamping (anaesthetic preconditioning, APC, group 5) which is known to induce cardioprotection (positive control group).

## Intervention

Administering Helium as preconditioning or postconditioning treatment. One group of patients will receive 3 * 5 minutes of Helium just before aortic cross clamping (preconditioning, PreC, group 2), another group will receive helium 3*5 min just before release of the aortic cross clamp (Postconditioning, PostC, group 3) and an additional group will receive both regimens (pre and postconditioning, PrePostC, group 4). One group of patients will serve as untreated controls (CON, group 1), and a positive control group will receive preconditioning with sevoflurane (3 * 5min) before aortic cross clamping (anaesthetic preconditioning, APC, group 5) which is known to induce cardioprotection (positive control group).

## Study burden and risks

Patients will receive total intravenous anaesthesia according to standard anaesthetic procedures. Helium (70% helium, 30% oxygen) will be administered to patients in the preconditioning groups. There are, up to now, no reports that helium has any relevant cardiovascular, pulmonary, allergic or other side effects. A gas-mixture of helium with oxygen (Heliox) is already in clinical

use for patients with severe asthma or for children undergoing mechanical ventilation.

## 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

Age: * 18 Years, Patients who have to undergo elective cardiac surgery (CABG without valve surgery), Written informed consent

### Exclusion criteria

Age * 18 years, Emergency operations, Pregnancy, Severe COPD, Absent informed consent,

SaO2 < 90% at room temperature, Presumed non cooperatives, Legal incapacity, Diabetes Mellitus, Renal failure, liver failure, Combined valve and coronary artery procedures,

# Study design

## Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2008 |
| Enrollment: | 125 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Helium |
| Generic name: | Heliox |
| Registration: | Yes - NL outside intended use |

# Ethics review

Approved WMO

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| Date: | 27-02-2008 |
| 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 |
|---|---|
| EudraCT | EUCTR2008-000992-12-NL |
| CCMO | NL22099.018.08 |