# The effect of helium inhalation on the coronary circulation and vessel diameter

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The primary objective is to investigate whether helium influences coronary artery circulation in humans undergoing elective percutaneous coronary interventions (PCI).

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

## Summary

### ID

NL-OMON35015

**Source**
ToetsingOnline

**Brief title**
Helium and the coronary circulation

### Condition

- Coronary artery disorders

**Synonym**
Coronary artery disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Cardioprotection, Coronary circulation, Helium

## Outcome measures

### Primary outcome

Coronary flow reserve (CFR) in the LAD

### Secondary outcome

- Fractional flow reserve (FFR) in the LAD

- MR in the LAD

- Lumen diameter of the RCx

- Vessel diameter of the RCx

- CFR in the RCx

- FFR in the RCx

- MR in the RCx

- Collateral flow index (CFI)

- Global hemodynamic parameters during helium application

- Complications during and following PCI

# Study description

### Background summary

In animal models of myocardial infarction, helium pre- and postconditioning has been shown promising results in the reduction of infarct size. Since helium, which is a registered medical gas, has no cardiovascular side-effects known until now, it could provide an attractive therapeutic agent to reduce ischemia reperfusion injury in clinical settings of ischemia-reperfusion, e.g. acute myocardial infarction. It appears that helium has no effects on hemodynamics. However, whether helium has any effect on the coronary circulation is not known. This study investigates whether helium influences on coronary flow, coronary pressure, microvascular resistance (MR) and vessel diameter of coronary arteries in humans.

### Study objective

The primary objective is to investigate whether helium influences coronary artery circulation in humans undergoing elective percutaneous coronary interventions (PCI).

### Study design

Open-label intervention study.

### Intervention

During the PCI procedure, participants will be breathing heliox21 (21 % oxygen + 79% helium) for periods of 10 minutes.

### Study burden and risks

Helium is used for mechanical ventilation of patients with pulmonary disease, e.g. asthma and chronic obstructive pulmonary diseases (COPD); thus far, no hemodynamic side-effects are described. The measurements carried out are considered part of normal patient care. Benefits for the study participants are not expected. However, if helium does provide cardioprotection this could be a safe way to improve the outcome of patients suffering from acute myocardial infarction. Before subjecting patients with acute myocardial infarction to helium inhalation we intend to investigate whether helium has any effects on coronary artery hemodynamics in humans.

## 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 PCI of the LAD
Age 18-80 years
Written informed consent

## Exclusion criteria

- Acute coronary syndrome
- Cardiogenic shock
- Prior coronary artery bypass grafting (CABG)
- Presence of a significant left main coronary artery stenosis (> 50% diameter stenosis)
- Diffuse disease
- Diabetes
- Severe pulmonary disease
- Kidney failure
- Liver failure
- Prior revascularisation
- Consecutive stenoses in a single artery
- Expected inability to complete the study protocol

# Study design

## Design

Study phase: 2

| | |
|---|---|
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-12-2009 |
| Enrollment: | 20 |
| Type: | Anticipated |

### Medical products/devices used

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

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 22-02-2010 |
| 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 | EUCTR2009-017014-80-NL |
| CCMO | NL30432.018.09 |