

# Does helium protect the heart against ischaemia-reperfusion damage in patients with acute myocardial infarction?

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To investigate whether the inhalation of helium during primary PCI can reduce the size of myocardial infarction.

<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-OMON34155

### Source

ToetsingOnline

### Brief title

Helium-MI

### Condition

- Coronary artery disorders

### Synonym

Myocardial infarction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw beurs voor translationeel onderzoek

## Intervention

**Keyword:** Cardioprotection, Helium, Ischemia reperfusion injury, Myocardial infarction

## Outcome measures

### Primary outcome

Infarct size as percentage of the area at risk, determined by MRI 2-4 days after PCI.

### Secondary outcome

MRI on day 2-4: infarct size, area-at-risk (=edema), left ventricular volumes (LVEDV, LVESV) and ejection fraction

MRI after 4 months: infarct size, left ventricular volumes (LVEDV, LVESV) and ejection fraction

Troponin: at baseline, 6 hours, 12 hours, 18 hours, 24 hours, 30 hours, 36 hours, 42 hours and 48 hours

NT-proBNP at baseline, 6 hours, 12 hours, 24 hours, 48 hours, 4 days and 4 months

MACE rate during 4 month follow-up

NYHA class at 30 days and 4 months

## Study description

### Background summary

Even when treated with a primary PCI, patients suffering from a myocardial infarction can sustain myocardial damage and loss of tissue, which has a negative effect on the outcome. In animal models of myocardial infarction, inhalation of helium has a protective effect and can reduce the amount of lost tissue. If this is the case in patients as well, helium inhalation can improve

the outcome of patients following myocardial infarction.

### **Study objective**

To investigate whether the inhalation of helium during primary PCI can reduce the size of myocardial infarction.

### **Study design**

Single center, randomised and placebo-controlled, investigator-blinded.

### **Intervention**

Inhalation of helium during the PCI until 10 minutes after opening of the target vessel.

### **Study burden and risks**

The risk associated with this study is limited; helium inhalation has no known side-effects and the MRI scans are safe unless contra-indicated (and those patients will be excluded). However, extra venapunctures (11 in total), 2x 30 minutes of scanning, a mailed questionnaire and 1 out-patient-visit (for the second scan), will be a minor inconvenience to the participants.

## **Contacts**

### **Public**

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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 18-75 years

STEMI, treatment with primary PCI

Chest pain duration less than 12 hours

### Exclusion criteria

Left bundle-branch block

Trombolytic therapy in the last 30 days

Prior infarction

Prior CABG

Left main stenosis, requiring CABG

Mechanical ventilation

High catecholamines usages

IABP or Impella

Glibenclamide usage

Kidney failure

Contraindication for MRI

## Study design

### Design

Study phase: 2

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	70
Type:	Anticipated

## Medical products/devices used

Product type:	Medicine
Brand name:	Heliox
Generic name:	Helium

## Ethics review

Approved WMO	
Date:	24-11-2010
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**

EudraCT

CCMO

**ID**

EUCTR2010-022393-13-NL

NL33604.018.10