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

Published: 24-11-2010
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To investigate whether the inhalation of helium during rpimary PCI can reduces the size of myocardial infarction.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	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 primairy 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, ionhalation 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 rpimary PCI can reduces the size of myocardial infarction.

Study design

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

Intervention

Inhalation of helium during the PCI untill 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 venapunctions (11 in total), 2x 30 minutes of scanning, a mailed questionaire and 1 out-patient-visit (for the second scan), will be a minor inconvenience the the participants.

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 18-75 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
Prio 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	ID
EudraCT	EUCTR2010-022393-13-NL
CCMO	NL33604.018.10