The use of Helium in acute myocardial infarction trial (HAMI-trial).

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23814

Source
NTR

Brief title
HAMI-trial

Health condition

Acute myocardial infarction
acute coronary syndrome
ischemia reperfusion injury
acuut hartinfarct
acuut coronair syndroom
ischemie reperfusie schade

Sponsors and support

Primary sponsor: Academical Medical Center, University of Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

On day 4 after the PCI a CMR will be obtained. T-2 weighed imaging shows edema in the tissue which has been ischemic before and is therefore at risk for developing infarction. T-1 weighed imaging after the injection of gadolinium contrast marks the infarcted tissue. Primary endpoint is the total volume of infarction as proportion of the total volume of myocardium at risk.

Secondary outcome

CMR measurements:

1. On day 2-4: Left ventricular function, left ventricular dimensions, infarct size, edema;

2. After 4 months: Left ventricular function, left ventricular dimensions, infarct size;

3. Biomarker release following the PCI: Troponin T, NT-proBNP;

4. Time of ST-segment resolution after opening of the target vessel;

5. Thrombolysis in myocardial infarction (TIMI);

6. Grade Flow following opening of the target vessel;

7. Occurrence of death, re-infarction and admission for heart failure at 30 days and 4 months following PCI;

8. New York heart Association functional class at 30 days and 4 months following PCI.

Study description

Background summary

In patients with acute myocardial infarction swift revascularistion is the treatment of choice. However, even after PCI tissue dmage continous: ischemia reperfusion injury. In animal models, helium inhalation has been shown to reduce this kind of damage. In this study we investigate whether cotreatment with helium during primairy PCI reduces the size of myocardial infarction in patients.

Study objective

We hypothesize that helium postconditioning reduces ischemia reperfusion injury following an acute myocardial infarction and thereby reduces the size of infarction. Secondly, we hypothesize that this reduction leads to improved myocardial function, less adverse events and less limitations during daily life of the respective patients.

Study design

Blood samples will be obtained for analysis of troponin T levels at baseline and at 6 hour intervals during the first two days. NT-proBNP levels will be determined at baseline, 6 hours, 12 hours, 24 hours, 48 hours and at 4 days and 4 months after the procedure. Analysis of all the samples will be done in the central laboratory for clinical chemistry at the AMC.

Intervention

Helium inhalation (79%) starting directly after inclusion, untill 10 minutes after opening of the target vessel.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-75 years;

2. ST-elevation myocardial infarction;

3. Treatment with primary PCI;

4. Chest pain of <12 hours duration.

Exclusion criteria

1. Left bundle branch block;

2. Previous myocardial infarction;

3. Fibrinolytic treatment in the previous 30 days;

4. Previous coronary artery bypass surgery;

5. Left main stenosis requiring coronary bypass surgery;

6. Severe heart failure as witnessed by any of the following:

A. The need for mechanical ventilation;

B. The use of an intra-aortic balloon pump or Impella;

C. High catecholamine usage.

7. Usage of the anti-diabetic drug glibenclamide (this drug is known to block any conditioning effect);

8. Renal failure;

9. Inability to undergo MRI (e.g. due to the presence of pacemaker or ICD).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-02-2011
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion Date:	14-01-2011
Application type:	First submission

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
NTR-new	NL2566
NTR-old	NTR2691
Other	METC AMC Amsterdam / CCMO : 10/210 / NL 33604.018.10 ;

Study results

Summary results
N/A