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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23814

Bron
NTR

Verkorte titel
HAMI-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Academical Medical Center, University of Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-75 years;

2. ST-elevation myocardial infarction;

3. Treatment with primary PCI;

4. Chest pain of <12 hours duration.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2566
NTR-old	NTR2691
Ander register	METC AMC Amsterdam / CCMO : 10/210 / NL 33604.018.10 ;

Resultaten

Samenvatting resultaten
N/A