HEBE III: A prospective, randomised, double blind, placebo controlled clinical study to examine the effects of a single bolus erythropoietin on left ventricular function in patients with an acute myocardial infarction.

Gepubliceerd: 15-05-2006 Laatst bijgewerkt: 18-08-2022

A single bolus EPO administered just before a primary PCI for a first acute myocardial infarction will increase left ventricular function after 4 months.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26840

Bron
NTR

Verkorte titel
HEBE III

Aandoening

One group will receive the study medication and the other group will receive placebo medication.

Ondersteuning

Primaire sponsor: Inter Cardiological Institute Netherlands
Van Buchem Stichting (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint will be left ventricular ejection faction, measured with Cardiac Magnetic Resonance Imaging at 4 months after onset of the acute myocardial infarction.

Toelichting onderzoek

Achtergrond van het onderzoek

Erythropoetin (EPO) is commonly known as an effective treatment for anemia, (partly) caused by an inadequate production of endogenous EPO (e.g., renal failure). However, we and others suggested several important extra-hematopoeitic effects of EPO, which might be beneficial in the setting of an acute myocardial infarction. Recent animal studies provided very consistent evidence for a reduced infarct size and improved left ventricular function caused by EPO administration. In addition, we and others have mainly explained the beneficial effects of EPO by non-hematopoietic effects, such as reduction of apoptosis and stimulation of neovascularisation.
Clinical studies with EPO in non-anemic patients are scarce. However, in our safety study, EPO administration in patients with an acute myocardial infarction was safe and well tolerated. Therefore the primary objective of this study is to establish the effects of a single bolus EPO administered just before a primary PCI for a first acute myocardial infarction, on left ventricular function after 4 months.

Doel van het onderzoek

A single bolus EPO administered just before a primary PCI for a first acute myocardial infarction will increase left ventricular function after 4 months.

Onderzoeksproduct en/of interventie

1. One bolus of EPO (Eprex, about 60.000 IU) will be administered intravenously in 30 minutes, within 3 hours after the primary PCI procedure. OR
2. Placebo

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Successful primary PCI (TIMI 2/3) for a first acute myocardial infarction, diagnosed by:
1. Chest pain suggestive for acute myocardial infarction;
2. Symptom onset < 12 hour after hospital admission, or < 24 hour in case ongoing ischemia;
3. ECG with ST-T segment elevation > 1 mV in 2 or more leads;
4. TIMI flow 0/1 before primary PCI on diagnostic coronary angiography.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Hemoglobin levels > 10.6 mmol/L;
2. Anticipated additional revascularisation within 4 months;
3. Cardiogenic shock;
4. Presence of other serious medical conditions;
5. Pregnancy/breast feeding;
6. Malignant hypertension;
7. End stage renal failure (kreatinin > 220 micromol/l);
8. Previous treatment with rh-EPO;

9. Blood transfusion <12 weeks prior to randomisation;
10. Allergy against rh-EPO;
11. Polycytemia verae;
12. Previous acute myocardial infarction;
13. Concomitant inflammatory or malignant disease;
14. Recent trauma or major surgery;
15. Unwilling to sign informed consent;
16. Contra-indications for MRI (pacemaker and other metal subjects).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL619
NTR-old	NTR678
Ander register	: N/A
ISRCTN	ISRCTN46528154

Resultaten

Samenvatting resultaten
N/A