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.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26840

Source
NTR

Brief title
HEBE III

Health condition

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

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary study endpoints are:

1. Myocardial infarct size, summarised as the percentage of left ventricular mass, measured with Cardiac Magnetic Resonance Imaging at 4 months after onset of the acute myocardial infarction;

2. Cardiovascular events (cardiovascular death, re-myocardial infarction, re-PCI or CABG, stroke, heart failure) from the onset of the acute myocardial infarction to 4 months afterwards;

3. Enzymatic infarct size with computerised measurements of CK and CK-MB;

4. Safety endpoint: Incidence of death, stroke, onset or worsening of CHF, deep vein thrombosis, malignant hypertension (RR>250/125), re-myocardial infarction, pulmonary embolism, seizure.

Study description

Background summary

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.

Study objective

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	400
Type:	Anticipated

Ethics review

Not applicable

Application type: Not applicable

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	NL619
NTR-old	NTR678
Other	: N/A
ISRCTN	ISRCTN46528154

Study results

Summary results
N/A