

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

Submission date 26/05/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/05/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/02/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00449488

Protocol serial number

N/A

Study information

Scientific Title

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

Acronym

HEBE III

Study objectives

A single bolus erythropoietin (EPO) administered just before a primary percutaneous coronary intervention (PCI) for a first acute myocardial infarction will increase left ventricular function after four months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval details not yet received as of 26/05/06

Study design

Prospective, randomised, double-blind, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Myocard infarction

Interventions

One bolus of EPO (Eprex, about 60.000 IU) will be administered intravenously in 30 minutes, within 3 hours after the primary PCI procedure versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Erythropoietin

Primary outcome(s)

The main study endpoint will be left ventricular ejection fraction, measured with cardiac magnetic resonance imaging at four months after onset of the acute myocardial infarction

Key secondary outcome(s)

Secondary study endpoints are:

1. Myocardial infarct size, summarised as the percentage of left ventricular mass, measured with cardiac magnetic resonance imaging at four months after onset of the acute myocardial infarction
2. Cardiovascular events (cardiovascular death, re-myocardial infarction, re-PCI or coronary artery bypass graft (CABG), stroke, heart failure) from the onset of the acute myocardial infarction to four months afterwards
3. Enzymatic infarct size with computerised measurements of creatine kinase (CK) and creatine kinase myocardial band (CK-MB)
4. Safety endpoint: incidence of death, stroke, onset or worsening of congestive heart failure (CHF), deep vein thrombosis, malignant hypertension (risk ratio [RR] >250/125), re-myocardial infarction, pulmonary embolism, seizure

Completion date

01/09/2008

Eligibility

Key inclusion criteria

Successful primary PCI (thrombin inhibition in myocardial infarction [TIMI] 2/3) for a first acute myocardial infarction, diagnosed by:

1. Chest pain suggestive of acute myocardial infarction
2. Symptom onset <12 hours after hospital admission, or <24 hours in case ongoing ischemia
3. Electrocardiogram (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 spinotheralamic tract

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Hemoglobin levels >10.6 mmol/l
2. Anticipated additional revascularisation within four months
3. Cardiogenic shock
4. Presence of other serious medical conditions
5. Pregnant/breast feeding
6. Malignant hypertension
7. End stage renal failure (creatinine >220 micromol/l)

8. Previous treatment with recombinant human erythropoietin (rh-EPO)
9. Blood transfusion <12 weeks prior to randomisation
10. Allergy against rh-EPO
11. Polycythemia vera
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 magnetic resonance imaging (MRI) (pacemaker and other metal subjects)

Date of first enrolment

01/09/2006

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen (UMCG)

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

University/education

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010	07/02/2019	Yes	No
Protocol article	protocol	01/05/2008	07/02/2019	Yes	No