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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/05/2006	**Overall study status** Completed	
Last Edited 07/02/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00449488

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2006

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 spinothalamic tract

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

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)
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Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

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Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Groningen (UMCG) and Interuniversity Institute of Cardiology (ICIN), The Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/05/2008	07/02/2019	Yes	No

Results article	results	01/11/2010	07/02/2019	Yes	No