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Multicenter, randomised trial of intracoronary infusion of autologous mononuclear bone marrow cells or peripheral mononuclear blood cells after primary percutaneous coronary intervention (PCI)

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 10/10/2014	**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

Secondary identifying numbers
NTR166

Study information

Scientific Title

Acronym
HEBE

Study objectives
The primary objective of this study is to determine whether intracoronary infusion of autologous mononuclear bone marrow cells or peripheral mononuclear blood cells provides improved recovery of regional left ventricular function after an acute, large myocardial infarction treated by percutaneous coronary intervention (PCI) compared to standard therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
After written informed consent has been obtained, MRI measurements and echocardiography are performed minimally 48 hours after PCI. Patients are randomised to a treatment with:

1. Intracoronary infusion of autologous mononuclear bone marrow cells
2. Intracoronary infusion of peripheral mononuclear blood cells
3. Standard therapy

If applicable, bone marrow is aspirated from the iliac crest under local anaesthesia or venous blood is collected. Mononuclear cells are isolated from the aspirate or blood by density gradient centrifugation. Within 7 days after PCI and within 24 hours after bone marrow aspiration or venous blood collection, a catheterisation for the intracoronary infusion of the autologous mononuclear cells in the infarct related coronary artery is performed. In all patients the follow up is at 1, 4 and 12 months. The MRI measurements and catheterisation are repeated at 4 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The change of regional myocardial function based on a MRI-segmental analysis at four months relative to baseline.

Secondary outcome measures
1. Functional: change of LV ejection fraction at four months relative to baseline, measured by MRI and echocardiography, and change in global and regional wall motion severity index (WMSI) measured by echocardiography at 4 months and 12 months relative to baseline
2. Infarct related: change of infarct size at 4 months relative to baseline, measured by MRI
3. Clinical: occurrence within 4 and 12 months of a major adverse cardiac events
4. Angiograpic: the presence of in-stent restenosis and late luminal loss
5. Change of intracoronary haemodynamic parameters at 4 months relative to baseline

Overall study start date
23/06/2005

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. PCI within 12 hours of onset of symptoms
2. Successful treatment of a culprit lesion in the left anterior descending (LAD), right coronary artery (RCA) or ramus circumflexus (RCX)
3. At least one creatine kinase (CK) and/or creatine kina-myocardial bands (CK-MB) measurement 10 times higher than the local upper limit of normal (ULN)
4. Hypokinesia or akinesia of greater than or equal to three segments using a 16-segment model documented by routine resting echocardiography at least 12 hours after primary PCI
5. Clinically and haemodynamically stable over the previous 12 hours

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Less than 30 or greater than 70 years of age
2. Anticipated percutaneous or surgical coronary intervention within the next four months
3. Presence of supraventricular or ventricular arrhythmias
4. Left ventricular (LV) ejection fraction less than 45% prior to current admission for myocardial infarction
5. Stroke or transient ischaemic attack within the previous 24 hours
6. Any contraindication for magnetic resonance imaging (MRI)
7. Positive for human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
8. Serious known concomitant disease with a life expectancy of less than one year

Date of first enrolment
23/06/2005

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center Amsterdam,
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Interuniversity Cardiology Institute of the Netherlands (ICIN) (Netherlands)

Sponsor details
P.O. Box 19258
Utrecht
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3501 DG

Sponsor type
Research organisation

ROR
https://ror.org/01mh6b283

Funder(s)

Funder type
University/education

Funder Name
Interuniversity Cardiology Institute of the Netherlands (ICIN) (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?
Results article	results	01/07/2011		Yes	No
Results article	results	01/08/2011		Yes	No
Results article	results	01/03/2015		Yes	No