Multicenter, randomized trial of intracoronary infusion of autologous mononuclear bone marrow cells or peripheral mononuclear blood cells after primary PCI.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27593

Source
Nationaal Trial Register

Brief title
HEBE-trial

Health condition

Acute myocardial infarction

Sponsors and support

Primary sponsor: Interuniversity Institute of Cardiology of the Netherlands (ICIN), Utrecht, the Netherlands
Source(s) of monetary or material Support: Interuniversity Institute of Cardiology of the Netherlands (ICIN), Utrecht, the Netherlands.

Intervention

Outcome measures

Primary outcome

The change of regional myocardial function based on a MRI-segmental analysis at 4 months relative to baseline.

Secondary outcome

Functional:

change of LV ejection fraction at 4 months relative to baseline, measured by MRI and echocardiography, and change in global and regional WMSI measured by echocardiography at 4 months and 12 months relative to baseline;

Infarct related:

change of infarct size at 4 months relative to baseline, measured by MRI;

Clinical:

occurrence within 4 and 12 months of a major adverse cardiac events;

Angiograpic:

the presence of in-stent restenosis and late luminal loss;

Change:

of intracoronary hemodynamic parameters at 4 months relative to baseline.

Study description

Background summary

N/A

Study objective

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 PCI compared to standard therapy.

Study design

N/A

Intervention

After written informed consent has been obtained, MRI measurements and echocardiography are performed minimally 48 hours after PCI. Patients are randomized to a treatment with
1. Intracoronary infusion of autologous mononuclear bone marrow cells;
2. Intracoronary infusion of peripheral mononuclear blood cells; or
3. Standard therapy.
If applicable, bone marrow is aspirated from the iliac crest under local anesthesia 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 catheterization 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 catheterization are repeated at 4 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. PCI within 12 hours of onset of symptoms;

2. Successful treatment of a culprit lesion in the LAD, RCA or RCX;

3. At least one CK and/or CK-MB measurement 10 times higher than the local ULN;

4. hypokinesia or akinesia of >=3 segments using a 16-segment model documented by routine resting echocardiography at least 12 hours after primary PCI;

5. Clinically and hemodynamically stable over the previous 12 hours.

Exclusion criteria

1. <30 or >70 years of age;

2. Anticipated percutaneous or surgical coronary intervention within the next 4 months;

3. Presence of supraventricular or ventricular arrhythmias;

4. LV ejection fraction < 45% prior to current admission for myocardial infarction;

5. Stroke or transient ischemic attack within the previous 24 hours;

6. Any contraindication for MRI;

7. Positive for HIV, HBV or HCV infection;

8. Serious known concomitant disease with a life expectancy of less than one year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2005
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	30-08-2005
Application type:	First submission

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	NL132
NTR-old	NTR166
Other	: N/A
ISRCTN	ISRCTN95796863

Study results

Summary results
N/A