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

Gepubliceerd: 30-08-2005 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27593

Bron
Nationaal Trial Register

Verkorte titel
HEBE-trial

Aandoening

Acute myocardial infarction

Ondersteuning

Primaire sponsor: Interuniversity Institute of Cardiology of the Netherlands (ICIN), Utrecht, the Netherlands
Overige ondersteuning: Interuniversity Institute of Cardiology of the Netherlands (ICIN), Utrecht, the Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-06-2005
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL132
NTR-old	NTR166
Ander register	: N/A
ISRCTN	ISRCTN95796863

Resultaten

Samenvatting resultaten
N/A