Mesenchymal stem cells after acute myocardial infarction.

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Intramyocardial injection of autologous mesenchymal stem cell injection after myocardial infarction may enhance recovery of myocardial function by stimulation of angiogenesis or regeneration of cardiomyocytes.

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

Samenvatting

ID

NL-OMON24674

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Acute myocardial infarction

Ondersteuning

Primaire sponsor: Investigator-initiated study.
Principal investigator: dr. D.E. Atsma
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Safety and feasibility of intramyocardial injection of ex vivo expanded mesenchymal stem

cells after primary PTCA for acute myocardial infarction

Toelichting onderzoek

Achtergrond van het onderzoek

Recently, stem cell transplantation has been proposed to serve as a novel therapeutic option in patients with acute myocardial infarction. In experimental studies, stem cell application to infarcted myocardium led to a decrease in infarct size, a decrease in apoptosis, a positive effect on left ventricular remodeling, increased contractile performance and an increase in survival of mice with experimental myocardial infarction. In the clinical setting, several randomized trials have been conducted which investigated the effect of intracoronary bone marrow-derived mononuclear cell injection. However, scarce data are available with regard to ex-vivo expanded mesenchymal stem cells. This study investigates the safety and feasibility of intramyocardial injection of ex-vivo expanded autologous bone marrow-derived mesenchymal stem cells in patients with myocardial infarction. Therefore, bone marrow aspiration will be performed 2-3 days after myocardial infarction, and cultured mesenchymal stem cells will be injected in the myocardium with an injection catheter (NOGA system). Safety will be monitored using holter registrations, laboratory measurements and clinical follow-up. Furthermore, effects on cardiac perfusion and function will be assessed with the us of echocardiography and gated-SPECT.

Doel van het onderzoek

Intramyocardial injection of autologous mesenchymal stem cell injection after myocardial infarction may enhance recovery of myocardial function by stimulation of angiogenesis or regeneration of cardiomyocytes.

Onderzoeksopzet

Baseline and 3 months follow-up.

Onderzoeksproduct en/of interventie

- Bone marrow cell aspiration from the iliac crest

- Ex-vivo expansion of mesenchymal stem cells

- Intramyocardial injection (by catheterization) of expanded mesenchymal stem cells

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Acute ST segment elevation myocardial infarction treated by successful primary PTCA of the infarct related coronary artery within 12 hours after onset of chest pain

2. Increase in CPK levels >1600 U/L

3. Male or female >18 years old

4. Able and willing to undergo all the tests used in the protocol

5. Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous myocardial infarction or CABG

2. Evidence of cancer (except low grade and fully resolved non-melanoma skin malignancy)

3. Concurrent participation in a study using an experimental drug or an experimental procedure within 2 months before acute myocardial infarction

4. Unstable medical situation e.g. life-threatening heart failure

5. Other severe concurrent illnesses (e.g. active infection, aortic stenosis, renal failure)

6. Bleeding diathesis or HIV infection

7. Any other condition that, in the opinion of the investigator, could pose a significant threat to the subject if the investigational therapy was to be initiated

8. Candidates for additional surgical or percutaneous intervention within the study period

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-11-2008
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	NL1483
NTR-old	NTR1553
Ander register	: P.05.179
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A