Mesenchymal stem cells after acute myocardial infarction.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24674

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Acute myocardial infarction

Sponsors and support

Primary sponsor: Investigator-initiated study.
Principal investigator: dr. D.E. Atsma
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

- Safety and feasibility of intramyocardial injection of ex vivo expanded mesenchymal stem cells after primary PTCA for acute myocardial infarction

Secondary outcome

- To assess the efficacy of autologous bone marrow-derived in vitro expanded mesenchymal stem cell transplantation after successful primary PTCA for acute myocardial infarction:

- Infarct size assessed by gated SPECT (baseline vs. 3 months)

- Left ventricular ejection fraction, left ventricular end-diastolic volume and left ventricular end-systolic volume as assessed by gated SPECT (baseline vs. 3 months)

Study description

Background summary

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.

Study objective

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.

Study design

Baseline and 3 months follow-up.

Intervention

- Bone marrow cell aspiration from the iliac crest

- Ex-vivo expansion of mesenchymal stem cells

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2006
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-11-2008
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	NL1483
NTR-old	NTR1553
Other	: P.05.179
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A