Randomized, double blind, placebo controlled trial of intramyocardial injection of autologous bone marrow cells in no-option patients with refractory angina pectoris and documented ischemia.

No registrations found.

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

Summary

ID

NL-OMON29227

Source
NTR

Brief title
N/A

Health condition

Refractory angina pectoris and documented myocardial ischemia.

Sponsors and support

Primary sponsor: Departmartement of Cardiology,
Leiden University Medical Center ,
Leiden,
the Netherlands
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The change in myocardial perfusion (SPECT) at 3 monhts follow-up relative to baseline.

Secondary outcome

EFFICACY:

Clinical end points:

1. Angina frequency;

2. Canadian cardiovascular society score;
3. Quality of life;

4. Exercise capacity;

Functional end points:

5. Change in LV ejection fraction at 3 monhts follow-up;

6. Regional myocardial function on a segmental base at 3 monhts follow-up;

Safety:

7. Occurence of ahrrythmias;

8. Pericardial effusion > 5 mm (echo);
9. Myocardial damage;

10. Severe inflammation.

Study description

Background summary

After written informed consent has been obtained, quality of life and exercise capacity will be investigated.
In addition myocardial function and perfusion will be documented.
Bone marrow will be aspired from the iliac crest under local anesthesia.
Patients will be randomised to receive bone marrow cells or placebo. In all patients NOGA mapping will be performed with subsequent intramyocardial injection of autologous bone marrow-derived mononuclear cells or placebo.
Quality of life and exercise capacity will be reassessed at 3 and 6 monhts follow-up. In addition, changes in myocardial function and perfusion will be evaluated at 3 months follow-up.

Study objective

The aim of this study is to determine the safety and efficacy of intramyocardial injection of autologous bone marrow cells in no-option patients with refractory angina pectoris and documented myocardial ischemia.

Study design

N/A

Intervention

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Contacts

Public
Leiden University Medical Center (LUMC)
Department of Cardiology
Postal zone: C5-P
P.O. Box 9600
Jan Ramshorst, van
Leiden 2300 RC
The Netherlands
+31 (0)71 5262020

Scientific
Leiden University Medical Center (LUMC)
Department of Cardiology
Postal zone: C5-P
P.O. Box 9600
Jan Ramshorst, van
Leiden 2300 RC
The Netherlands
+31 (0)71 5262020

Eligibility criteria

Inclusion criteria

1. Severe refractory angina despite optimal medical therapy;

2. Reversible ischemia on GATED-SPECT;

3. No candidate for (repeat) revascularization (CABG or PCI);

4. Male or female, > 18 years old;

5. Patients must be stable (e.g. not be in a setting of life-threatening heart failure);

6. Written informed consent.

Exclusion criteria

1. Acute myocardial infarction, PCI or CABG within 6 months of enrolment in the study;

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

3. Unexplained haematological or biochemical abnormalities;

4. Concurrent participation in a study using an experimental drug or an experimental procedure within 6 months before the injection procedure;

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

6. Bleeding diathesis or HIV infection;

7. Inability to follow the protocol and comply with follow-up requirements.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2005
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	13-09-2005
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	NL361
NTR-old	NTR400
Other	: N/A
ISRCTN	ISRCTN58194927

Study results

Summary results
N/A