Efficacy assessment of REpeat intramyocardial INJECTion of autologous bone marrow cells in previously responding no-option patients with residual or recurrent refractory Angina Pectoris and documented ischemia.

No registrations found.

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

Summary

ID

NL-OMON20190

Source
Nationaal Trial Register

Brief title
RE-INJECT AP

Health condition

refractory angina pectoris
bone marrow cell
intramyocardial injection

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Department of Cardiology
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

The change in myocardial perfusion at 3 months follow-up relative to baseline.

Secondary outcome

Clinical end points:

1. Canadian cardiovascular society score;

2. Quality of life (translated Seattle angina questionnaire);

3. Exercise capacity.

Functional end points:

1. Left ventricular ejection fraction at 3 monhts follow-up.

Safety:

1. Occurence of ahrrythmias;

2. Pericardial effusion > 5 mm (echo);

3. Myocardial damage;

4. Severe inflammation.

Study description

Background summary

N/A

Study objective

The aim of this study is determining whether repeat intramyocardial injection of bone marrow cells is safe and effective in the treatment of refractionary angina pectoris.

Study design

At 3 and 6 months follow-up.

Intervention

1. After written informed consent has been obtained, quality of life and exercise capacity will be investigated. Myocardial perfusion and function will be documented;

2. Bone marrow will be aspired from the iliac crest under local or general anesthesia;

3. In all patients NOGA mapping will be performed with subsequent intramyocardial injection of autologous bone marrow-derived mononuclear cells;

4. Quality of life, ccs class and exercise capacity will be reassessed at 3 and 6 monhts follow-up. In addition, changes in myocardial function perfusion and function will be evaluated at 3 months follow-up.

Contacts

Public
Leiden University Medical Center
Department of Cardiology
Postbus 9600
D.E. Atsma
Albinusdreef 2

Leiden 2300 RC
The Netherlands
+31 (0)71 5262020
Scientific
Leiden University Medical Center
Department of Cardiology
Postbus 9600
D.E. Atsma
Albinusdreef 2

Leiden 2300 RC
The Netherlands
+31 (0)71 5262020

Eligibility criteria

Inclusion criteria

1. Having received intramyocardial bone marrow cell injection in study P02.051 (Injection of Autologous Bone Marrow Cells into Damaged Myocardium of No-option Patients with Refractory Angina Pectoris and Ischemia, a two-phased study of safety, feasibility and efficacy) or P05.025 (Efficacy assessment of intramyocardial injection of autologous bone marrow cells in no-option patients with refractory angina pectoris and documented ischemia, a randomized, double blind, placebo controlled study);

2. Disabling refractory angina pectoris despite optimal medical therapy;

3. Residual reversible ischemia on GATED-SPECT imaging;

4. No candidate for (repeat) revascularization;

5. Male or female, > 18 years old;

6. Patients must be stable and not be in a setting of life-threatening heart failure (LVEF>35%);

7. Able to perform an exercise tolerance test prior to therapy;

8. Able and willing to undergo all the tests used in this protocol including the traveling involved;

9. Written informed consent.

Exclusion criteria

1. Evidence of cancer (except low grade and fully resolved non-melanoma skin malignancy) as bone marrow cell infusion might promote tumor growth through induction of angiogenesis in the tumor;

2. Concurrent participation in a study using an experimental drug or an experimental procedure within 2 months before the injection procedure;

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

4. Bleeding diathesis or HIV infection;

5. 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;

6. Inability to undergo cardiac catheterization or nuclear testing;

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

8. Candidates for surgical of percutaneous intervention;

9. Mechanical aortic valve prosthesis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2010
Enrollment:	23
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-12-2010
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	NL2546
NTR-old	NTR2664
CCMO	NL30970.000.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A