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

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/01/2013	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S L M A Beeres

Contact details
Leiden University Medical Centre
Department of Cardiology
P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 2020
s.l.m.a.beeres@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR400

Study information

Scientific Title

Study objectives
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 ischaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, double-blind, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Angina pectoris, myocardial ischaemia

Interventions
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 re-assessed at 3 and 6 months follow-up. In addition, changes in myocardial function and perfusion will be evaluated at 3 months follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The change in myocardial perfusion (SPECT) at 3 months follow-up relative to baseline.

Secondary outcome measures
Efficacy:
1. Clinical end points:
1.1. Angina frequency
1.2. Canadian cardiovascular society score
1.3. Quality of life
1.4. Exercise capacity
2. Functional end points:
2.1. Change in left ventricular (LV) ejection fraction at 3 months follow-up
2.2. Regional myocardial function on a segmental base at 3 months follow-up
3. Safety:
3.1. Occurrence of arrhythmias
3.2. Pericardial effusion greater than 5 mm (echo)
3.3. Myocardial damage
3.4. Severe inflammation

Overall study start date
01/05/2005

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Severe refractory angina despite optimal medical therapy
2. Reversible ischaemia on gated-single photon emission computed tomography (SPECT)
3. Not a candidate for (repeat) revascularisation (coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI])
4. Male or female, greater than 18 years old
5. Patients must be stable (e.g. not be in a setting of life-threatening heart failure)
6. Written informed consent

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key 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 human immunodeficiency virus (HIV) infection
7. Inability to follow the protocol and comply with follow-up requirements

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details

Department of Cardiology
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
Hospital/treatment centre

Website
http://www.lumc.nl/english/start_english.html

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/05/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	01/11/2012		Yes	No