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.

Gepubliceerd: 13-09-2005 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON29227

Bron
NTR

Verkorte titel
N/A

Aandoening

Refractory angina pectoris and documented myocardial ischemia.

Ondersteuning

Primaire sponsor: Departmartement of Cardiology,
Leiden University Medical Center ,
Leiden,
the Netherlands

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2005
Aantal proefpersonen:	50

Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2005
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	NL361
NTR-old	NTR400
Ander register	: N/A
ISRCTN	ISRCTN58194927

Resultaten

Samenvatting resultaten

N/A