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.

Gepubliceerd: 23-12-2010 Laatst bijgewerkt: 13-12-2022

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.

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

Samenvatting

ID

NL-OMON20190

Bron
Nationaal Trial Register

Verkorte titel
RE-INJECT AP

Aandoening

refractory angina pectoris
bone marrow cell
intramyocardial injection

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Cardiology
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

At 3 and 6 months follow-up.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-12-2010
Aantal proefpersonen:	23
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A