Injection of Autologous Bone Marrow Cells into Damaged Myocardium of No-option Patients with Ischemic Heart Failure, a randomized placebo-controlled trial.

Gepubliceerd: 16-09-2010 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 severe ischemic heart failure.

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

Samenvatting

ID

NL-OMON23517

Bron
NTR

Aandoening

heart failure, bone marrow cells

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The change in left ventricular ejection fraction at 3 monhts follow-up relative to baseline.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

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 severe ischemic heart failure.

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. In addition myocardial perfusion, viability and sympatic innervation and function will be documented;

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

3. 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;

4. Quality of life and exercise capacity will be reassessed at 3 and 6 monhts follow-up. In addition, changes in myocardial function perfusion, viability and sympatic innervation 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. Ischemic heart failure NYHA class 2, 3 or 4 despite optimal pharmacological and non-pharmacological therapy;

2. No candidate for (repeat) surgery (revascularization, valve repair or ventricular reconstruction);

3. No candidate for (repeat) percutaneous revascularization;

4. Optimal resynchronization therapy or no candidate for resynchronization therapy;

5. Male or female, > 18 years and < 75 years old;

6. Life expectancy more than 6 months;

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);

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

3. Other severe concurrent illnesses (including active infection, aortic stenosis defined as aortic valve area below 1.0cm2, severe renal insufficiency defined as a GFR <30 mL/min/1.73m2);

4. Bleeding diathesis, HIV infection or pregnancy;

5. Any other condition that, in the opinion of the investigator, could pose a significant threat to the subject if the investigational therapy will be initiated;

6. Inability to undergo cardiac catheterization or nuclear testing;

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

8. Candidate for surgery (revascularization, valve repair or ventricular reconstruction), resynchronization therapy or percutaneous revascularization.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart

(Verwachte) startdatum:	26-04-2010
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2010
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	NL2408
NTR-old	NTR2516
Ander register	CME / CCMO : P10.081 / NL21184.000.09 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A