Intramuscular or combined intramuscular/intra-arterial administration of bone marrow mononuclear cells in patients with advanced limb ischemia.

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The primary aim of our study was to test the feasibility and safety of exclusively intramuscular, and combined intramuscular/intra-arterial delivery of Bone marrow Mononuclear Cells (BMC) in patients with advanced without conventional options for...

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

Samenvatting

ID

NL-OMON22349

Bron
NTR

Verkorte titel
N/A

Aandoening

Limb ischemia, stem cells, bone marrow cells, vasculogenesis, arteriogenesis.

(NLD: Perifeer vaatlijden, stamcellen, beenmerg, arteriogenese).

Ondersteuning

Primaire sponsor: Leiden University Medical Center.
Overige ondersteuning: Leiden University Medical Center.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Wound healing / limb salvage (Fontaine 3/4);
2. Painfree walking distance (Fontaine 2).

Toelichting onderzoek

Achtergrond van het onderzoek

A substantial number of patients with severe peripheral arterial occlusive disease (PAOD) is left without technical options for surgical or endovascular treatment. Recent evidence suggests that bone marrow mononuclear cells (BMC) may promote collateral vessel formation in these patients. However, several critical aspects such as long-term safety, effect durability, and optimal administration mode require consideration. We evaluated feasibility and safety of exclusively intramuscular versus combined intramuscular/intra-arterial delivery of BMC in patients with severe PAOD who were not candidates for surgical or endovascular treatment.

Doel van het onderzoek

The primary aim of our study was to test the feasibility and safety of exclusively intramuscular, and combined intramuscular/intra-arterial delivery of Bone marrow Mononuclear Cells (BMC) in patients with advanced without conventional options for surgical or endovascular treatment.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Hospital admittance was planned in a short-stay setting (24-48 hrs). The harvest procedure was performed according to standard protocols for bone marrow donation for allogenic transplantation. 750 milliliter bone marrow was collected from the posterior iliac crest under epidural or general anesthesia. The suspension was filtered and subsequently concentrated in a final volume of 40 mL. Upon concentration of the BMC-fraction, the erythrocyte fraction was collected separately and reinfused to the patient.

The mononuclear cells were implanted approximately 4 h after bone marrow aspiration. The method of administration was randomly assigned to the patients using a random number

table: either by local injection into the gastrocnemius muscle or by combined IM+IA delivery. The investigators were not blinded for the assignment. In case of total IM delivery, we implanted 1 ml using a 26-gauge needle on 40 sites, 1.5 cm deep, using the full surface of the gastrocnemius muscle. In patients assigned to the combined treatment arm, the volume of each IM injection was 0.5 ml. The remaining 20 ml was slowly infused after selective catheterization of the superficial femoral artery (or profunda femoral artery in case of occlusion of the SFA), performed according to the standard procedures within the department of radiology.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Disabling claudication (Fontaine’s stages IIb/III or Rutherford’s categories 3/4) or critical limb ischemia (Fontaine’s stages IV or Rutherford’s categories 5/6) despite > 6 months optimal medical therapy;

2. Ineligibility for angioplasty or bypass procedures;

3. Male of female, >18 years old;

4. Life expectancy > 1 year;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Candidates for angioplasty or bypass procedures;

2. Inability to undergo bone marrow harvesting;

3. Life threatening co-morbidity;

4. INR >2;

5. History of malignant disease in 5 years prior to treatment;

6. Inability to undergo arterial catheterization;

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

8. Any other conditions that, in the opinion of the investigators, could interfere with the therapy or could pose a significant threat to the subject if the investigational therapy was to be initiated.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2004

Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-06-2007
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	NL970
NTR-old	NTR997
Ander register	:
ISRCTN	ISRCTN76049483

Resultaten

Samenvatting resultaten
J Cardiovasc Surg (Torino). 2008 Feb;49(1):51-8.