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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22349

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

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

Sponsors and support

Primary sponsor: Leiden University Medical Center.
Source(s) of monetary or material Support: Leiden University Medical Center.

Intervention

Outcome measures

Primary outcome

1. Wound healing / limb salvage (Fontaine 3/4);

2. Painfree walking distance (Fontaine 2).

Secondary outcome

1. Ankle/brachial index;

2. Brief Pain Inventory.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-01-2004
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion Date:	13-06-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL970
NTR-old	NTR997
Other	:
ISRCTN	ISRCTN76049483

Study results

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