The Dutch LimFlow registry; a clinical post marketing trial investigating the long term results after a Percutaneous Deep Vein Arterialization (LimFlow) in the treatment of no-option chronic limb threatening ischemia patient.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21714

Source
NTR

Brief title
Dutch LimFlow Registry

Health condition

Chronic limb threatening ischemia

Sponsors and support

Primary sponsor: LimFlow
Source(s) of monetary or material Support: LimFlow

Intervention

Outcome measures

Primary outcome

Amputation-free survival at 24 months follow-up

Secondary outcome

Secondary objectives are to evaluate the long-term effect of pDVA on:
- Complete wound healing
- Primary and secondary patency
- Limb salvage
- Renal function
- Quality of life
- Long term cardial effect
- Cost effectiveness

Study description

Background summary

Chronic limb threatening ischemia (CLTI) is the clinical end stage of peripheral artery disease (PAD) and is associated with high amputation, mortality rates and poor quality of life. For CLTI patients with no revascularization options, venous arterialization could be an alternative technique for limb salvage. A recent development, is the Percutaneous Deep Vein Arterialization (pDVA) which is a novel, minimally invasive, endovascular approach to perform a venous arterialization procedure. Major advantage of this approach is the minimal invasiveness with lower periprocedural risks and no creation of wounds in an already critically ischemic leg. Our hypothesis is that in patients with no-option CLTI, a treatment with pDVA is a feasible, safe, and a clinically effective approach. Therefore, we initiated a prospective clinical cohort trial to investigate the outcome of the pDVA in no-option CLTI patients in the Netherlands.
The study population consists of patients with a clinical diagnosis of symptomatic CLTI, defined as Rutherford category 4, 5 or 6 with the assessment that no conventional surgical or endovascular treatment is possible. The patients will undergo a percutaneous deep vein arterialization (pDVA).
Our primary outcome is amputation free survival. Secondary endpoints are complete wound healing, primary and secondary patency, limb salvage, renal function, quality of Life, cardial effect and cost effectiveness.

Study objective

Our hypothesis is that in patients with no-option critical limb ischemia, a treatment with

pDVA is a feasible, safe and a clinically effective approach.

Study design

12 months and 24 months follow-up

Intervention

Percutaneous deep venous arterialization

Contacts

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Eligibility criteria

Inclusion criteria

I-1. Approved for the LimFlow procedure
I-2. Subject is willing and has adequate support to comply with protocol requirements, including medication regimen and followup visits

Exclusion criteria

E-1. Patient unable to give consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-11-2019
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	NL8158
Other	Approved by the METC VUmc as non-WMO study : 2019-335

Study results