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.

Gepubliceerd: 13-11-2019 Laatst bijgewerkt: 13-12-2022

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.

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

Samenvatting

ID

NL-OMON21714

Bron
NTR

Verkorte titel
Dutch LimFlow Registry

Aandoening

Chronic limb threatening ischemia

Ondersteuning

Primaire sponsor: LimFlow
Overige ondersteuning: LimFlow

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Amputation-free survival at 24 months follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

12 months and 24 months follow-up

Onderzoeksproduct en/of interventie

Percutaneous deep venous arterialization

Contactpersonen

Publiek

Northwest Clinics
Eline Huizing

072 548 4444

Wetenschappelijk

Northwest Clinics
Eline Huizing

072 548 4444

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

E-1. Patient unable to give consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-11-2019
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	NL8158
Ander register	Approved by the METC VUmc as non-WMO study : 2019-335

Resultaten