Dutch Critical Limb Ischemia Registry

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New endovascular techniques, such as stents or drug-coated devices, demonstrate superior (patency and limb salvage) outcomes compared to conventional plain old balloon angioplasty (POBA) for critical limb ischemia (CLI) patients based on arterial...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25441

Bron
NTR

Verkorte titel
THRILLER

Aandoening

Peripheral arterial disease
Critical Limb ischemia

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Primary patency: freedom from clinically driven target lesion revascularization (CD-TLR) or a significant restenosis or occlusion on imaging.

- Limb salvage: freedom from major amputations (above the ankle).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The prevalence of peripheral arterial disease (PAD) is still rising. The end stage of PAD is critical limb ischemia (CLI) and is associated with high amputation- and mortality rates and low quality of life. CLI typically presents as crural or pedal arterial pathology. Despite international guidelines, there is still clinical variation in the treatment of CLI.
Objective: To investigate the best endovascular treatment modality in patients with CLI based on arterial pathology below the knee
Study design: A prospective multi-center cohort study.
Study population: Patients (≥ 18 years) with CLI based on arterial pathology below the knee.
Main study endpoints: The primary endpoints are limb salvage and primary patency. Limb salvage is defined as freedom from major amputations, i.e. amputations above the ankle. Primary patency is defined as freedom from clinically-driven target lesion revascularization (CD-TLR) and a significant restenosis on imaging.
Nature and extent of burden: No additional actions are required and no additional risks are taken by included patients. This study will not influence patient care.

Doel van het onderzoek

New endovascular techniques, such as stents or drug-coated devices, demonstrate superior (patency and limb salvage) outcomes compared to conventional plain old balloon angioplasty (POBA) for critical limb ischemia (CLI) patients based on arterial pathology below the knee.

Onderzoeksopzet

6 weeks, 6 months, 12 months, 24 months

Onderzoeksproduct en/of interventie

An endovascular intervention on the below the knee arteries can imply plain old balloon angioplasty (POBA) with or without additional treatment modalities, such as vessel preparation devices, stenting or drug-coated devices.

Contactpersonen

Publiek

UMC Utrecht
Michael Nugteren

0625226813

Wetenschappelijk

UMC Utrecht
Michael Nugteren

0625226813

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients ≥ 18 years with critical limb ischemia (CLI) who undergo an endovascular intervention of the below the knee (BTK) segment.
- Patients treated in the P2 or P3 segments of the popliteal artery are included.
- Patients who undergo a failed attempt of endovascular revascularization (''no option'' critical ischemia) will also be included.
- Patients who underwent previous (endovascular) surgery in the same segment or who undergo simultaneous revascularization in other arterial segments will also be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who undergo an endovascular intervention in the P1 segment of the popliteal artery or more proximal segment.
- Patients who don't meet the inclusion criteria

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	1000
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:	07-01-2021
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	NL9192

Register	ID
Ander register	METc VUmc : 2020.0609

Resultaten