The effect of arterial disease level on the outcomes of supervised exercise in intermittent claudication: the ELECT Registry

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There is no clinically relevant difference regarding changes in maxium walking distance between intermittent claudication patients with aortoiliac and femoropopliteal disease after supervised exercise therapy.

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27644

Bron
Nationaal Trial Register

Verkorte titel
ELECT Registry

Aandoening

Peripheral arterial disease, intermittent claudication

Ondersteuning

Primaire sponsor: Catharina Hospital Eindhoven
Overige ondersteuning: Initiatior

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in maximum walking distance on a standardized treadmill test after 3, 6 and 12 months of SET.

Toelichting onderzoek

Achtergrond van het onderzoek

Despite guideline recommendations advocating conservative management before invasive treatment in intermittent claudication, early revascularisation remains widespread in patients with favourable anatomy. The aim of the ELECT Registry is to determine the effect of the location of stenosis on the outcomes of supervised exercise in patients with intermittent claudication due to peripheral arterial disease.

This multicentre prospective cohort study aims to enrol 320 patients in ten vascular centres across the Netherlands. All patients diagnosed with intermittent claudication (peripheral arterial disease: Fontaine II/Rutherford 1-3), who are considered candidates for supervised exercise therapy by their own physicians are appropriate to participate. Participants will receive standard care, meaning supervised exercise therapy first, with endovascular or open revascularization in case of insufficient effect.

For the primary objectives, patients are grouped according to anatomical characteristics of disease (aortoiliac, femoropopliteal, or multilevel disease) as apparent on the preferred imaging modality in the participating centre (either duplex, CTA, or MRA). Changes in walking performance (treadmill tests, 6-minute walk test) and quality of life (QoL; Vascular QoL Questionnaire-6, World Health Organization QoL Questionnaire-Bref) will be compared between groups, after multivariate adjustment for possible confounders. Furthermore, freedom from revascularization and major adverse cardiovascular disease events, and attainment of the treatment goal between anatomical groups will be compared.

Doel van het onderzoek

There is no clinically relevant difference regarding changes in maxium walking distance between intermittent claudication patients with aortoiliac and femoropopliteal disease after supervised exercise therapy.

Onderzoeksopzet

Timepoints are mentioned with the outcome measures of interest above. For the primary outcome: 3, 6 and 12 months.

Onderzoeksproduct en/of interventie

Participants will receive standard care, meaning SET first, with endovascular or open revascularization in case of insufficient effect.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Intermittent claudication (IC) due to peripheral arterial disease (PAD; Fontaine II, Rutherford 1-3)

- Ankle brachial index (ABI) <0.9 or drop in ABI > 0.15 after an exercise test.

- Candidate for supervised exercise therapy (SET) as a primary treatment, at the discretion of the treating vascular surgeon.

- Recent or planned imaging of at least the aortoiliac and femoropopliteal tract (within 6 months of SET initiation): either colour Duplex Scanning or computed tomography angiography (CTA) or magnetic resonance angiography (MRA).

- Signed informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Advanced PAD beyond IC (i.e. ischemic rest pain and/or ulcers, Fontaine >II, Rutherford 4-6).

- High probability of non-adherence to physician¡¦s, or physical therapist¡¦s follow-up requirements.

- Current participation in a concurrent trial that may confound study results.

- Vascular intervention as primary treatment, at the discretion of the treating vascular surgeon.

- Prior SET, performed in accordance with the guidelines of the Dutch Society for Physical Therapists, in the previous 12 months.

- Prior revascularization in the lower-extremities in the previous 12 months.

- Neurogenic/venous/orthopedic claudication more dominant than arterial claudication complaints.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	26-10-2017
Aantal proefpersonen:	320
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7135
NTR-old	NTR7332
Ander register	MEC-U : W17.071

Resultaten