(Cost-)Effectiveness of lower extremity nerve decompression surgery in diabetic subjects: the DeCompression (DECO) trial

Gepubliceerd: 15-04-2019 Laatst bijgewerkt: 13-12-2022

LEND surgery is a (cost)-effective treatment option for patients with Diabetes and lower extremity compression neuropathy, compared to conventional (non-surgical) care.

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

Samenvatting

ID

NL-OMON20505

Bron
Nationaal Trial Register

Verkorte titel
DECO-trial

Aandoening

Diabetes Mellitus
Neuropathy
Compression neuropathy

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary objective: to study the influence of LEND surgery on disease-specific quality of life as measured on the Norfolk-QoL-DN questionnaire, at 48 months follow-up.
Primary endpoint: the difference between the total Norfolk-QoL-DN score at baseline compared to the score at 48 months between the intervention and control group.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The peripheral nerves of patients with diabetes are often pathologically swollen, which results in entrapment at places of anatomical narrowing. This results in nerve dysfunction. Surgical treatment of compression neuropathies in the lower extremities (LEND) results in relief of complaints and gain in peripheral nerve function, which may result in less sensory loss (short term) and less associated detrimental effects including foot ulceration and amputations, and lower costs (long term).

Objective: Evaluation of the effectiveness and (cost-)effectiveness of surgical decompression of compressed lower extremity nerves (LEND surgery) compared to patients 'treated' with conventional (non-surgical) care.

Study design: A stratified randomized (1 to 1) controlled trial comparing LEND surgery (intervention) with conventional (non-surgical) care (control strategy). Randomisation is stratified for participating hospital and number of nerves involved. Patients and controls have the same follow-up at 1.5, 3, 6, 9, 12, 18, 24, 36 and 48 months. Participants will be recruited in 12 months and enrolled in eleven affiliated hospitals, in which they receive both intervention or conventional (non-surgical) care and follow-up. Outcome assessors are blinded to group assignment.

Study population: Primary eligibility criteria are patients with diabetes (≥ 18 years old) with complaints of neuropathy and a bilateral Tinel sign at the tarsal tunnel (tibial nerve) as signs of compression neuropathies in the lower extremity.

Intervention (if applicable): In the intervention group, a surgical release of up to four lower extremity nerves (tibial, common, superficial, and deep peroneal nerves) will be carried out. The contralateral leg will be operated three months later.

Main study parameters/endpoints: Complaints (Norfolk QoL-DN), health-related quality of life (EQ-5D, SF-36), plantar sensation, incidence of ulcerations/amputations and resource use during follow-up. The incremental cost-utility ratio will be estimated on the basis of the collected empirical data and a cost-utility model.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks associated with participation are related to the surgical procedure. Up to four peripheral nerves in the lower extremity are decompressed, with a contralateral procedure after 12 weeks of the first surgery. The surgical procedure is safe in this vulnerable

group, with acceptable low rates of complications rates reported. Reported complications are haemorrhage, wound dehiscence and wound infection(1). Current best diabetes and diabetic foot care are provided to both groups. Nine times a physical examination is carried out in both the intervention and control group, together with quality of life and resource use data collection. The physical examination includes sensory testing, electrodiagnostic measurements and gait analysis, all of which are safe to conduct, with no physical or physiological discomfort associated with participation. To reduce patient burden, not all examinations are executed on all follow-up moments and some outcome measures are assessed in a sub selection of participating centers. Benefit for patients include regular monitoring of their foot status, with early detection of potential threatening conditions.

Doel van het onderzoek

LEND surgery is a (cost)-effective treatment option for patients with Diabetes and lower extremity compression neuropathy, compared to conventional (non-surgical) care.

Onderzoeksopzet

First year: inclusion period
Follow up period: 4 years

Onderzoeksproduct en/of interventie

Lower extremity Nerve Decompression surgery

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Having diabetes mellitus (type 1 or 2)
• Patients (> 17 and < 76 years old)
• Symptoms of neuropathy (assessed with the MNSI, scoring > 3)
• A bilateral Tinel sign at the tarsal tunnel (posterior tibial nerve)
• Sufficient circulation to heal lower-extremity incisions (by palpating the peripheral arteries of the foot: a palpable dorsal pedis artery or posterior tibial artery is needed). In case of non-palpable arteries a pedal Doppler arterial waveform is evaluated. A toe brachial index is performed when the Doppler signal is not triphasic
• Minimal or controlled pedal edema (assessed with inspection and physical examination)
• Being fit for surgery
• Compliant with instructions for their own care
• Intact protective sensation (cutaneous threshold <10 g monofilament) at the plantar side of the foot (plantar hallux and fifth toe)
• Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• DFU(s) or amputation(s) in history, active radicular syndrome or neurological disease interfering with sensation of the feet, as assessed in the interview and screening questionnaire (e.g. HIV and chemotherapy induced neuropathy)
• Previous surgery at lower extremity nerve compression sites
• Active Charcot foot
• Not able to understand written and oral instructions (i.e. insufficient command of Dutch language)
• Being incompetent (incapacitated)
• Current enrollment in a clinical trial which involves surgery of the lower extremity or medical drug trials investigating the effects on neuropathy symptoms.
• HbA1c level > 11% at baseline
• Pregnant women

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	344
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:	15-04-2019
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	NL7664
Ander register	METC UMC Utrecht : ABR: NL68312.041.19

Resultaten