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

No registrations found.

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

Summary

ID

NL-OMON20505

Source
Nationaal Trial Register

Brief title
DECO-trial

Health condition

Diabetes Mellitus
Neuropathy
Compression neuropathy

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Short term:
1) To study the influence of LEND surgery on balance and gait parameters at 24 months.
Endpoint: the difference between pedobarographic and pedothermographic imaging results between the intervention and control group.
2) To study to what extent pre-operative electrodiagnostic studies (used to grade the severeness of DSP) account for the variation in surgical outcome (HRQoL: Norfolk-QoL-DN, SF-36, EQ-5D) at 24 months.
Endpoint: the influence of electrodiagnostic parameters (CMAP, DML, SNAP) on the difference in scores of the HRQoL between the intervention and control group.
3) To study to what extent pre-operative nerve damage influences the results of LEND surgery on balance and gait parameters, VAS neuropathy scores, HRQoL and symptoms at 24 months.
Endpoint: the influence of RDF Test Battery scores on the difference in balance and gait parameters, VAS neuropathy scores, HRQoL and symptoms (MNSI) between the intervention and control group.

Long term:
1) To study if LEND surgery is (cost)effective, compared to current care (HRQoL, resource use, productivity loss), at 48 months.
Endpoint: the difference between HRQoL, resource use (based on data from hospital financial systems, general practitioner, national databases) and productivity loss (iMCQ and iPCQ) between the intervention and control group. Cost-effectiveness will be evaluated as the incremental cost-utility ratio (ICUR/ICER) of LEND surgery compared to current best care
2) The influence of LEND surgery on gain in sensory function (measured with the RDF Test Battery) at 48 months.
Endpoint: the difference in RDF Test Battery scores between the intervention and control group
3) To study to what extent this surgical procedure results in lower risk of diabetic foot ulceration, amputation and falls at 48 months.
Endpoint: the difference in incident diabetic foot ulceration, amputation and falls between the intervention and control group.
4) To study to what extent pre-operative nerve damage influence the results of LEND surgery (i.e. HRQoL, sensory function and the incidence of ulceration, amputation and falls) at 48 months.
Endpoint: the difference in HRQoL, RDF Test Battery scores, incident ulceration, amputation and falls between the intervention and control group.

Study description

Background summary

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.

Study objective

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

Study design

First year: inclusion period
Follow up period: 4 years

Intervention

Lower extremity Nerve Decompression surgery

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	344

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 15-04-2019

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	NL7664
Other	METC UMC Utrecht : ABR: NL68312.041.19

Study results