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

Published: 19-09-2019
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Evaluation of the (cost-)effectiveness of surgical decompression of compressed lower extremity nerves (LEND surgery) compared to patients 'treated' with conventional best care.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON54529

Source
ToetsingOnline

Brief title
DECO trial

Condition

- Peripheral neuropathies
- Nervous system, skull and spine therapeutic procedures

Synonym
diabetic foot, Neuropathy, polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW,Stichting Coolsingel

Intervention

Keyword: Amputation, Lower Extremity Nerve Decompression Surgery, Neuropathy, Ulceration

Outcome measures

Primary outcome

Complaints (Norfolk QoL-DN).

Secondary outcome

Quality of life (EQ-5D5L, 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.

Study description

Background summary

RESEARCH QUESTION: Evaluation of the (cost-)effectiveness of surgical decompression of compressed lower extremity nerves (LEND surgery) compared to non-surgical, conventional care.

HYPOTHESIS: Our hypothesis is that the surgical treatment of compression neuropathies in the lower extremity results in relief of complaints and gain in peripheral nerve function, which may result in less sensory loss and the detrimental effects associated with this, such as diabetic foot ulceration and amputations and the associated costs. LEND surgery is expected to be incrementally cost-effective compared to current best care. STUDY DESIGN: Multicenter randomized controlled trial. Comparison of the (cost-)effectiveness of LEND surgery compared to current non-surgical care. STUDY

POPULATION / DATA RESOURCES: Adult patients with diabetes with neuropathy complaints and compression neuropathies in the lower extremity.

INTERVENTION: decompression of compressed lower extremity nerves.
USUAL CARE/COMPARISON: Conventional non-surgical care.

OUTCOME MEASURES Complaints (Norfolk QoL-DN), quality of life (EQ-5D5L, SF-36), plantar sensation, incidence of ulcerations/amputations, balance and gait and electrodiagnostic parameters, resource use during follow-up. The incremental cost-utility ratio will be estimated on the basis of the collected empirical data.

SAMPLE SIZE / DATA ANALYSIS 258 patients are needed to show a difference of 15% in quality of life (total Norfolk-Qol-DN score between baseline and follow-up)(1; 2). Adjusting for an anticipated 25% lost to follow-up renders our total study size to be 344 patients (129*100/75 = 172 patients per group). Between 28 and 40 patients will be included per center (11 participating centers in total). The primary analysis will be performed by using repeated measurements ANOVA (change in Norfolk-QoL-DN between baseline and follow-up). Patients will be analysed according to the intention-to-treat principle.

COST-EFFECTIVENESS ANALYSIS / BUDGET IMPACT ANALYSIS Medical and societal costs will be evaluated, so potential restoration of function and gain in quality of life can be weighed against the incremental costs of surgery.

BURDEN / RISK: Time investment per patient is on average 10 hours for the total study period. The risks are related to the surgery itself (wound healing problems and hemorrhage) and are accepted as generally being a low.

TIME SCHEDULE Start: Start inclusion of patients: September 2019. Last follow-up: September 2024

Study objective

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

Study design

A stratified randomized (1 to 1) controlled trial comparing LEND surgery (intervention) with current best care (control strategy). Patients and controls have the same follow-up at 1.5, 3, 6, 9, 12, 18, 24 and 48 months. Participants will be recruited in 12 months and enrolled in the eight affiliated hospitals, in which they receive both intervention and current best care and follow-up. Randomization is stratified for participating hospital. Outcome assessors are blinded to group assignment.

Intervention

In the intervention group, a surgical release of at least the tibial and common peroneal nerves, additional decompressions of the superficial and deep peroneal

nerves can be carried out when compressed. The contralateral leg will be operated three months later.

Study burden and risks

Negligible risk. Low impact on patients participating', only have to full in some questionnaires (± 10h for total study duration per patient).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 (n. tibialis posterior) Sufficient circulation to heal lower-extremity incision (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 oedema (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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2019
Enrollment:	344
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-06-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-10-2023
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL68312.041.19
Other	NL7664