Value of surgical decompression of the nerves of the lower extremities in patients with diabetic polyneuropathy: Lower Extremity Nerve entrapment Study (LENS).

No registrations found.

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

Summary

ID

NL-OMON27360

Source
NTR

Brief title
LENS

Health condition

Painful polyneuropathy diabetes mellitus surgery.

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Utrecht, The Netherlands
Source(s) of monetary or material Support: Nuts-OHRA

Intervention

Outcome measures

Primary outcome

Primary endpoint will be Visual Analogue Scale (VAS) <
2 or a significantly greater change in VAS in the treated limb compared with the contralateral limb after 6 months.

Secondary outcome

1. To study the influence of decompression on vibration perception threshold and tactile sensation;

2. To study the effect of decompression on prevention of foot ulcers and amputations;

3. To describe functional status of patients with diabetic
polyneuropathy;

4. To study the effect of decompression on functional status of patients with painful neuropathy;

5. To study if the posterior tibial nerve can anatomically recover after decompression of the tarsal tunnel. To study the reduction of edema in the tarsal tunnel and the thickness of the ligament covering the tarsal tunnel;

6. To study the effect of decompression on postural stability;

7. To study the effect of decompression on foot temperature as an autonomic nerve function;

8. To study the cost-effectiveness of surgical decompression of pedal nerves compared with medical therapy;

9. To study the effect of decompression on nerve conduction;

10. Health status measured with EQ-5D.

Study description

Background summary

Background:

Diabetic symmetrical peripheral neuropathy is a well known complication in patients with diabetes. The symptoms vary from a burning or itching sensation to pain or numbness. Because of diminished protective sensation, the risk of ulcers and amputations is increased. Medication
is helpful in treatment of pain in a limited number of patients with diabetic neuropathy, but does not prevent progression of neuropathy. There is some evidence that surgical

decompression of lower limb nerves is an effective intervention that relieves pain, restores sensation and
prevents foot ulcers and amputations in diabetic neuropathy.

Objective:

To evaluate the effect of surgical decompression of the nerves in the lower extremities on pain in patients with diabetic symmetrical neuropathy.

Design:

A randomized controlled clinical trial.

Center:

University Medical Center Utrecht, the Netherlands.

Intervention:

Over a period of two years 42 patients with diabetic neuropathy will be enrolled in this study. The intervention consists of surgical decompression of the nerves one of the lower limbs in these patients. Surgery will be performed within 8 weeks after randomisation. The contralateral limb, in which usual care is represented, will be used as
control, 'within patient comparison'. Patients will be tested for sensibility, quality of life, autonomous function, stability and nerve regeneration within the same time intervals. The last tests will be done one year after surgery.

Study objective

Surgical decompression of the nerves in the lower extremities in patients with diabetic symmetrical neuropathy improves symptoms.

Study design

6 months and 1 year post-surgery or post-enrollment.

Intervention

The intervention consists of surgical decompression of
the nerves of one lower limb in 42 patients. Surgery will be performed within 6 weeks after randomisation.

The contralateral limb will serve as a control. All patients will be treated with medication following the Dutch
Polyneuropathy Guideline.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with painful diabetic neuropathy, assessed
with the Diabetic Neuropathy Symptom score (DNS) and Diabetic Neuropathy Examination (DNE), aged between 18 and 90 will be included. All patients need to have a score of more than 2 on the Visual Analogue Scale (VAS), a positive Tinel sign of the posterior tibial and deep peroneal nerves
at the malleoli and dorsum of the foot and a positive Tinel sign of the common peroneal nerve at the proximal fibula. The Ankle-Brachial Index (ABI) should be between 0,8 and 1,15 with palpable peripheral pulsations in the posterior tibial artery and dorsal pedal artery, the Toe-Brachial index (TBI) ≥ 0.7.

Exclusion criteria

The Body Mass Index should not exceed 35 and the general condition has to be acceptable. The medical history should not include ankle fractures and patients with amputations proximal to the Lisfranc joint are excluded. Patients with ulcers on the foot are excluded. The patient has to be able to understand written en spoken instructions.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-05-2010
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	NL2219
NTR-old	NTR2344
Other	METC UMCU : 09-269
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A