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

Published: 28-10-2010
Last updated: 04-05-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON39394

Source
ToetsingOnline

Brief title
Lower Extremity Nerve entrapment Study (LENS)

Condition

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

Synonym
nerve entrapment caused by diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,fonds NutsOhra

Intervention

Keyword: decompression, diabetes, neuropathy, sensibility

Outcome measures

Primary outcome

To study the influence of decompression on pain.

Evaluation of pain with the Visual Analogue Scale.

The VAS will be used for both legs separately.

The VAS is a straight line, the ends of which are the extreme limits of the sensation being assessed. The line is 10 cm in length using a 10-point scale ranging from 1 to 10, with 1 being barely perceptible and 10 being intolerably painful. Primary endpoint will be VAS<2 or a significant greater change in VAS in the surgery group compared with the control group after 6 months.

Secondary outcome

To study the effect of decompression on vibration perceprion threshold and tactile sensation

Evaluation of the Vibration Perception Threshold (VPT) with the biothesiometer:

The VPT will be determined using a hand-held biothesiometer (Biomedical Instruments, Newbury, OH). VPT will be tested on the tip of the hallux. The biothesiometer is a device with a rubber probe that vibrates at 100 Hz. The

unit contains a linear scale that displays the applied voltage, ranging from 0 to 50 V. The voltage of vibration will be increased until the patient can perceive a vibration. The mean of three readings will be used to determine the VPT. A VPT value of >25V in at least one foot has been associated with a high cumulative risk of neuropathic ulceration. Values between 16 and 24V indicate intermediate risk and values <15, low risk. Secondary endpoints will be: significantly higher proportion of patients with VPT<25V in the surgery group or a significant lower mean VPT in the surgery group compared with the control group.

Evaluation of the tactile sensibility with the Semmes-Weinstein (monofilament), and two-point discriminator (TPD). With monofilament Semmes Weinstein, 10 plantar sites on the forefoot will be tested. The patient has to say Yes or No when asked if he/she believes the Semmes Weinstein monofilament is being applied. Inability to perceive the 10 g of force a 5.07 monofilament applies is associated with clinically large-fiber polyneuropathy.
Evaluation of the tactile sensibility with two-point discriminator (TPD). With TPD the minimum distance between two stimulus points on the skin perceived as disctinct points is measured. The foot is divided into ten standard significant areas. Secondary endpoints will be a significant difference in number of perceived applications after 6 months between the two groups.

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

To study the effect of decompression on functional status of patients with painful neuropathy.
Evaluation of the quality of life with the SF-36. Secondary endpoints will be a significant difference in score between the two groups after six months.

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 with ultrasound.
A secondary endpoint of the study is a significant difference between the two groups after six months.

To study the effect of decompression on postural stability with the SWAY, center of gravity.
To study the effect of decompression on foot temperature as an autonomic nerve function.
To study the cost-effectiveness of surgical decompression of pedal nerves compared with medical therapy.
To study the effect of surgical decompression on nerve conduction.
To study the effect on heat and cold perception thresholds (stimulus-response-function).

Study description

Background summary

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.

Study objective

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

Study design

A randomized controlled clinical trial.

Intervention

Decompression of the lower limb nerves includes: the posterior tibial nerve and its calcaneal, medial and lateral plantar branches at the ankle, the deep peroneal nerve over the dorsum of the foot, the common peroneal nerve near the head of the fibula and the superficial peroneal nerve at the calf .

Study burden and risks

Since all patients will be examined for vascular/arterial insufficiency, high risk patients can be excluded from this research project. Nevertheless patients who will undergo surgery will have 4 small incision. To minimize the risk for infection of the wound, the patient will receive antibiotics pre operatively. To optimize the woundhealing, patients are only allowed to mobilize with crutches after operation.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA

NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Painful Diabetic Neuropathy
positive Tinel sign
age 18-90;first control group: the same inclusion criteria but without diabetic neuropathy
second control group: people without diabetes mellitus and without neuropathy

Exclusion criteria

need for vascular surgical intervention of the extremity
ulcers on the foot
Sufficiënt treatment of pain with medication(VAS 0-1)
neuropathy caused by other factors than diabetes mellitus
patients with physical problems leading to instability;control group: anamnestic signs of periheral neuropathy
control group ultrasound: anamnastic signs of peripheral neuropathy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2011
Enrollment:	164
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-09-2013
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL29338.041.09