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

Gepubliceerd: 27-05-2010 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON27360

Bron
Nationaal Trial Register

Verkorte titel
LENS

Aandoening

Painful polyneuropathy diabetes mellitus surgery.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, Utrecht, The Netherlands
Overige ondersteuning: Nuts-OHRA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Po Box 85500
J.F.M. Macare van Maurik
Utrecht 3508 GA
The Netherlands
+31 (0)88 7556897

Wetenschappelijk

Po Box 85500
J.F.M. Macare van Maurik
Utrecht 3508 GA
The Netherlands
+31 (0)88 7556897

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2010
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	NL2219
NTR-old	NTR2344
Ander register	METC UMCU : 09-269
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A