Feasibility of Self-treatment of Painful Diabetic Neuropathy using Electrical Vasomotor Nerve Stimulation,

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Determining the feasibility of EVNS performed at home by the patient and/or caregiver, after instruction from the podiatrist.

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

Summary

ID

NL-OMON56887

Source
ToetsingOnline

Brief title
HOME-EVNS

Condition

- Peripheral neuropathies

Synonym
diabetic nerve damage, diabetic neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Neurecon BV
Source(s) of monetary or material Support: Neurecon BV

Intervention

Keyword: Diabetic, Neuropathy, Pain. Electrostimulation

Outcome measures

Primary outcome

i) The number and severity of reported side-effects of HOME-EVNS, gathered via telephonic consulting on treatment day 1,3 and 8 and via user-initiated incoming calls to the PI/SI

ii) Successful treatment defined as cycles with at least 8/10 successful (full 35 minutes) treatment sessions, derived from the adherence determined by recording device usage and intensity setting which is downloaded from device after its retrievalof having at least 8/10 adequate treatment sessions

iii) Usability, determined by the USER-Experience questionnaire (UEQ), and

iv) Number of help requests to service desk

Secondary outcome

i) Neuropathic Pain Symptom Inventory (NPSI)

ii) EQ-5D-5L, Quality of Life score

Study description

Background summary

Painful diabetic peripheral neuropathy (PDPN) affects a significant percentage of patients with diabetes mellitus in Europe and even more so in Africa and the Middle East. Various international, European, and North American guidelines recommend tricyclic agents (TCA), serotonin-norepinephrine reuptake inhibitors (SNRIs), and gamma-aminobutyric acid (GABA) analogues as first and second line treatments for PDPN, but there is no consensus on the use of morphine or tramadol. However, up to 75% of patients with PDPN do not respond to these treatments and require more advanced therapies to relieve pain. The economic

burden of PDPN is also significant. Specific forms of electrical stimulation (such as FREMS, a kind of electrical vasomotor nerve stmulation that use sequences of modulated electrical stimuli), has shown promise in reducing pain in patients with PDPN in randomized controlled trials. In a phase IV study the treatment proved effective and reduced medication use significantly. However, the treatment was given in an out patient setting, not favourable for the usually less mobile subjects. Therefore the current study is conducted using specific electrostimulation (EVNS) in the home setting.

Study objective

Determining the feasibility of EVNS performed at home by the patient and/or caregiver, after instruction from the podiatrist.

Study design

Intervention study

Intervention

The treatment with electrostimulation via EVNS is performed using the Releaf device (Neurecon, Vught, Netherlands). The technique utilizes four independent channels per leg, each with two pairs of electrodes. During the instruction, the optimal intensity for neurostimulation is set for each pair of electrodes by gradually increasing it until the patient perceives the sensation as intense but not painful. In the home setting, the patient can use and adjust this setting. This treatment is applied for 35 minutes per day for 10 consecutive days.

Study burden and risks

The specific time that participants spend on the treatment is 10 times 60 minutes over 10 consecutive days. Prior to this, an instruction session takes place with their own podiatrist; the rest of the treatment involves efforts in the home environment. The application is designed to be feasible in the home setting after the instruction. The entire procedure includes setting up the device and applying electrodes (15 minutes), the treatment itself (35 minutes), and disconnecting, cleaning up, and dressing (10 minutes).

The feasibility of the treatment and its effects will be assessed through the completion of seven questionnaires. The estimated time commitment per questionnaire (pre-treatment, after 1 month, and after 3 months) is expected to be a maximum of 20 minutes. Therefore, the total time commitment is estimated to be 660 minutes for the entire study.

No anticipated psychological discomfort is apparent. There is a helpdesk

available for any questions or issues.

No side effects have been reported previously from the electrostimulation.

Contacts

Public
Neurecon BV

Isabellastraat 9
Vught 5261 AG
AF
Scientific
Neurecon BV

Isabellastraat 9
Vught 5261 AG
AF

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Painful Diabetic Neuropathy refractory for at least 2 pharmacological interventions
Being in a mentall and physical state to perform home self-treatment with Releaf for 10 consecutive days or with adequate assistance of care-giver
Being in a mental and physical state to understand and complete the research questionnaires

Exclusion criteria

In case of other evident causes for painful neuropathy, significant peripheral arterial disease,
active foot ulceration, current alcohol or other substance abuse (use of alcohol over the recommended limits of less than 21 units of alcohol per week in men and 14 units in
women, presence of a medical device based on electrical stimulation, cardiac pacemaker and/or implantable cardioverter defibrillator or any other active implant*

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2024
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Releaf
Registration:	No

Ethics review

Approved WMO

Date:	11-07-2024
Application type:	First submission

Review commission: METC Brabant (Tilburg)

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	NL84421.000.23