The effectiveness of the Ness L-300 neuroprosthesis compared to the use of a conventional AFO or orthopaedic shoes (OSA) on walking activity of stroke patients

Published: 05-02-2007
Last updated: 14-05-2024

To compare the efficacy of the L300 with a conventional AFO or orthopedic shoes with regard to walking capacity in stroke patients suffering from a drop foot.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON31655

Source
ToetsingOnline

Brief title
L-300 peroneal nerve stimulation in stroke patients

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular Accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cerebrovascular Accident, orthotic device, Transcutaneous Electric Nerve Stimulation., walking

Outcome measures

Primary outcome

Walking activity measured with a StepWatch activity monitor mounted around the

ankle during 7 days.

Secondary outcome

functional gains, assessed with Goal Attainment Scaling

patient satisfaction, assessed with a questionnaire

comfortable walking speed (10 meter test) and the distance covered in 6-min

energy cost of walking estimated from oxygen uptake (VO2) measurement

gait parameters

Study description

Background summary

Many stroke patients have a spastic drop foot. These patients experience difficulty when walking because they are unable to effectively dorsiflex their ankle during the swing phase of walking.This lack of swing leg flexion predominantly causes stroke patients to experience difficulties while walking, due to insufficient foot clearance. The common treatment for drop foot is the prescription of an ankle-foot orthosis (AFO) or orthopaedic shoes. Most AFOs take away passive ankle motion in the frontal plane, while they limit plantar flexion at the ankle or provide an external dorsiflexion moment. Hence the major disadvantage of an AFO is the absence of normal ankle kinematics during gait, thereby reducing active ankle stability and related balance reactions.

Devices using functional electric stimulation (FES) have been introduced as an alternative treatment method for drop foot. The NESS L300® is a recently developed peroneal stimulator.

Study objective

To compare the efficacy of the L300 with a conventional AFO or orthopedic shoes with regard to walking capacity in stroke patients suffering from a drop foot.

Study design

A comparative, self-controlled study in which walking with the L300 will be compared to walking with AFO or Orthopedic Shoes.

Intervention

Use of peroneal stimulator Ness type L300 during 9 weeks. This device has a good fit ('one size fits all' principle) with constant positioning of 2 independent active electrodes. It has a very robust and reliable foot switch system that wirelessly communicates with the stimulation device mounted at the proximal side of the lower leg (just below the knee joint). The mode of electrical stimulation is such that patients can tolerate whole day use. The patient is able to don and doff the system independently.
In case of effectiveness (one of the functional goals attained, no complications and patient is compliant and satisfied with the use of L300) the duration of the intervention is prolonged to 12 months.

Study burden and risks

The burden consist of an intake visit with physical examination, a pre- and post-assessment consisting of walking tests, walking activity monitoring (during 7 days at home). Patients will use the L300 for 9 weeks with weekly control visits to the physiotherapist. During the whole study period subjects will keep a diary for recording fall- and near-fall accidents.
Participants wearing the L300 for 1 year will have 2 additional follow-up visits (post-assessments) at 6 and 12 months after inclusion.
The risks consist of a potential allergic reaction to stimulation and some muscle soreness in the beginning of the use of the L300. All adverse reactions are temporary.

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

chronic stroke (> 6 months post stroke)
drop foot
regular use of a polypropylene AFO or orthopaedic shoes ('OSA')
passive range of ankle motion >30 degrees, with neutral position in stance
ankle spasticity 0-3 as assessed by the Modified Ashworth Scale
independent walking ability (with or without walking aid) > 10 minutes.
Age 18-80 years
Able to visit the rehabilitation centre on multiple occasions during a 3 month period.
Superficial and deep peroneal nerve can be stimulated as well

Exclusion criteria

severe cognitive deficits
skin lesions at the electrode sites
pregnancy
psychological disorders (depression or psychosis)
participation in other investigation in the prior 6 months that may affect the study results

demand-type pacemaker

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2007
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	peroneal stimulator Type L-300
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL15798.018.06