The effects of a new FES device (NESS L300) on walking skills in stroke patients with a drop foot

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The main goal of this study is to evaluate the effectiveness of the NESS L300 on walking skills, as compared to a conventional ankle-foot orthosis, in stroke patients with a drop foot.

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

Summary

ID

NL-OMON30121

Source
ToetsingOnline

Brief title
The effects of the L300 on walking skills in stroke patients

Condition

- Central nervous system vascular disorders

Synonym
CVA, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Eigen middelen (Fonds WetenschapsBeoefening) aangevuld met sponsoring door industrie,NESS

Intervention

Keyword: Drop-foot, FES device, Gait analysis, Stroke

Outcome measures

Primary outcome

obstacle avoidance success rate

Secondary outcome

preferred walking velocity, step length and step width, duration of stance, swing, and double support phase, range of motion of ankle, knee, and hip during walking, EMG onset latency and amplitude in response to the obstacle, spatial avoidance characteristics (horizontal and vertical clearance margins), activity level, personal satisfaction, personal use.

Study description

Background summary

In the Netherlands, every year 30.000 people sustain a cerebrovasular accident (CVA or stroke). Although a large proportion of these people (approximately 60%) experience partly recovery, irreversible physical impairments remain. An estimated 20% of strokes result in a drop foot, which is caused by the inability to (efficiently) activate the muscles that dorsiflex the ankle joint. While walking, patients with a drop foot tend to drag the foot during the swing phase (lack of toe clearance), which places them at risk for tripping. Furthermore, a drop foot usually is part of a general stereotyped walking pattern of the affected leg, characterized by insufficient knee and hip flexion during swing. This lack of flexion predominantly causes stroke patients to experience difficulties when stepping over obstacles, due to insufficient foot clearance. Recently, a new device, using functional electrical stimulation, has been developed that enables separate activation of muscles involved in foot lift. The hypothesis is that the NESS L300 not only effectively lifts the foot during gait, but that it also reduces the stereotyped movement pattern of the affected leg. Walking skills are expected to improve on regular, but even more on irregular terrain. On irregular terrain, the locomotor pattern has to be adjusted continuously in order not to stumble or fall. These complex gait

skills are essential for independent and safe mobility in daily life. In this domain of gait skills, the NESS L300 is expected to be superior over conventional ankle-foot orthoses.

Study objective

The main goal of this study is to evaluate the effectiveness of the NESS L300 on walking skills, as compared to a conventional ankle-foot orthosis, in stroke patients with a drop foot.

Study design

Patients will be informed about this study by their physiatrists and eligible patients will be invited to participate. A 30-minute intake visit will be planned with one of the physiatrists of the department of rehabilitation of the Radboud University Nijmegen Medical Centre. After inclusion, physical activity will be monitored during a 7-day period by means of a pedometer. One to 2 weeks after the intake visit, a L300 system will de provided and adjusted to the patient. During the consecutive 2 weeks, each patient is given time to adapt to the system to be able to increase its use up to 6 hours per day. After these 2 weeks, a gait assessment will be scheduled at the mobility lab of the department of rehabilitation. During this visit, the quality of obstructed and unobstructed gait skills will be assessed when walking with the NESS L300 and when walking with a conventional AFO. The use of the L300 will be continued for another 6 weeks. In week 10 of the study, level of physical activity will be monitored for a second 7-day period. At the end of week 10 a second gait assessment will be conducted. During this visit, the quality of obstructed and unobstructed gait skills will be assessed once more when walking with the NESS L300 and when walking with a conventional AFO. Finally, the patient*s satisfaction with the use of the NES L300 will be evaluated. While using the L300, the patient will be contacted by telephone every week. The patient will be asked whether he/she experiences any difficulties using the NESS L300 and whether the daily use has been increased according to schedule. A more extensive telephone interview will be held in week 3, 4, 5, 7, and 10 of the study. In this interview the patient will be asked questions on the how many and which activities are currently being performed using the NESS L300.

Intervention

Daily use of the NESS L300 during 8 weeks

Study burden and risks

Burden associated with participation: see under 'Study design'

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18-80
- chronic stroke (> 6 months)
- drop-foot
- gebruik makend van een polypropyleen enkel-voetorthese
- Passive ankle range of motion > 30 degrees
- Ankle spasticity as measured by Modified Ashworth Scale: score 0-3
- Unassisted walking > 10 minutes

Exclusion criteria

- Severe cognitive deficit

- Skin lesions at electrode positions
- Pregnancy
- Depressive or psychotic disorder
- Pace-maker

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	L300 Neuroprosthesis Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL11831.091.06