The effects of an implantable FES device (Actigait) 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 Actigait on walking skills 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-OMON30837

Source
ToetsingOnline

Brief title
The effects of Actigait 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,Otto Bock BV

Intervention

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

Outcome measures

Primary outcome

- obstacle avoidance success rates (in terms of failures to avoid obstacles)

- net energy cost of walking at comfortable speed

Secondary outcome

- step length, step width, step frequency, cadence

- 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 toe clearance)

- ankle and knee moments and power during the stance phase of walking

- activity level (pedometer and questionnaire)

- comfortable walking speed (level walking normal surface)

- outdoor walking speed

- personal use (questionnaire)

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 (implanted) FES system has been developed for stroke patients with a drop foot. This system is expected to improve walking ability, not only on regular, but even more on irregular terrain. On irregular terrain, the locomotor pattern has to be continuously adjusted in order not to stumble or fall. These complex gait skills are essential for independent and safe mobility in daily life and highly associated with fall incidence. Especially in this domain of complex gait skills, Actigait® is expected to be superior to a conventional AFO or orthopedic shoes. Also walking efficiency, in terms of energy cost, is expected to benefit from the Actigait® system.

Study objective

The main goal of this study is to evaluate the effectiveness of Actigait on walking skills in stroke patients with a drop foot.

Study design

Step 1: Patients will be informed about this study by their physiatrists and eligible patients will be invited to participate. A 90-minute intake visit will be planned with the physiatrists of the department of rehabilitation in Nijmegen or Amsterdam. One week after the intake visit, an external FES system will be provided and adjusted to the patient. In addition, a baseline gait assessment will be scheduled at the mobility labs in Nijmegen and Amsterdam. During this visit, the quality of gait will be assessed when walking (if applicable, with AFO). After 4 weeks, the functional response to the external stimulation will be evaluated. When a good response to the external FES device is present, the patient will be admitted to step 2 of the study.
Step 2: The Actigait system will be implanted in a 45-minutes neurosurgical procedure. Ten days after surgery, the system will be set up and the patient can start its use. Repeated gait assessments will be conducted at 3 (Nijmegen only), 9, and 26 weeks, both with and without stimulation. In week 2, 3, 4, 6, 9 en 26 of step 2, a telephone interview will be held to evaluate the extent of usage and the activities performed with Actigait. Activity level will be monitored in week 1 of step 1 and in week 8 en 25 of step 2 by means of a pedometer.

Intervention

Implantation and usage of an FES system to correct drop foot

Study burden and risks

The common risks associated to (minor) surgical procedures to the extremities, like wound infections, apply to this study. The use of a cuff-electrode around the n. peroneus communis could theoretically lead to nerve damage when the electrode used is too small. In a prior study on the safety of the Actigait system by Burridge et al. (2007) no such events occurred. Furthermore, no additional device-related adverse events occurred during a 15-months follow-up period.

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
- insufficient therapeutic effects of conventional treatment methods, such as an AFO, orthopedic footwear, or discomfort with the use of these orthotic devices
- passive range of ankle motion > 30 degrees with at least 0 degrees of dorsiflexion with extended knee on physical examination
- ankle spasticity 0-3 as assessed by the Modified Ashworth Scale
- independent walking ability without walking aid for > 10 minutes
- age 18-60 years
- able to visit the academic hospitals in both Nijmegen and Amsterdam on multiple occasions during a nine-months period
- positive response to an external peroneal stimulation

Exclusion criteria

- Severe cognitive deficit
- 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):	01-09-2007
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Implantable Neuroprosthesis

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	NL17811.091.07