The long-term effects of an implanted drop foot stimulator (ActiGait®) on walking capacity in patients with stroke

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

Summary

ID

NL-OMON34481

Source
ToetsingOnline

Brief title
Long term effects of ActiGait 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: TWIN - Instituut voor Neuromodulatie

Intervention

Keyword: Drop foot, Functional Electrical Stimulation, Gait, Stroke

Outcome measures

Primary outcome

Primary outcomes:

- Emory Functional Ambulation Profile (E-FAP) score.

Secondary outcome

Secondary outcomes:

- 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

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

- spatial obstacle avoidance characteristics during E-FAP obstacle sub-test

(horizontal and vertical toe clearance)

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

E-FAP obstacle sub-score)

- the ratio of cMAP (as the peripheral evoked motor response) and MEP (as the

centrally generated motor response)

Utility measures:

- both 10-m and 6-minute comfortable walking speed (level walking normal

surface)

- activity level (pedometer)

- SIS-scores (Stroke Impact Scale) + social participation domain

- PASIPD-scores (Physical Activity Scale for Individuals with Physical

Disabilities)

- personal use (questionnaire)

Study description

Background summary

In the Netherlands, every year approximately 40.000 persons sustain a cerebrovascular accident (CVA or stroke). An estimated 20% of all stroke survivors suffer from a *drop foot*, which is caused by the inability to (selectively) 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 is usually part of a more generalized stereotyped movement pattern of the affected leg, characterized by insufficient knee and hip flexion during the swing phase. This lack of swing leg flexion predominantly causes stroke patients to experience difficulties when stepping over obstacles, due to insufficient foot clearance. In stroke patients with a drop foot, the common treatment is the prescription of an ankle-foot orthosis (AFO). Devices using functional electrical stimulation (FES) have been introduced as an alternative treatment method for drop foot. These devices artificially activate the muscles that dorsiflex and evert the ankle joint during the swing phase of gait. Actigait®, an internal FES system, directly stimulates the common peroneal nerve through 4 distinct electrodes embedded in a cuff, that is surgically placed around the nerve. The stimulation device selectively controls the 4 electrodes within the cuff, in order to differentiate between fibers predominantly branching to the superficial peroneal nerve (activating the peroneal muscles) and those to the deep peroneal nerve (activating the anterior tibial muscle).
The first hypothesis of the proposed study is that the Actigait® system will not only effectively and selectively elevate and control the ankle joint during the swing and early stance phase, but that it will reduce the stereotyped movement pattern of the affected leg (see above) as well. This may result in an improvement of the quick, online adaptability of the step. On irregular terrain, the locomotor pattern has to be continuously adjusted in order not to stumble or fall. Therefore, 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. Preliminary results from our previous study confirm this hypothesis and the proposed study is necessary to further explore the potential effectivity of ActiGait® in a

broader patient population.
A second aspect of the proposed study is the possible training effects of FES. Over time, volitional control of movement may improve with FES as a consequence of motor re-learning. However, until now, the evidence for training effects of peroneal FES is not yet convincing. In addition, in studies that found such training effects, the adaptation mechanisms underlying these effects remained poorly understood. Neuroplastic changes of peripheral as well as central structures may contribute to the observed benefits. For example, muscle fibers may be strengthened and the recruitment of spinal motorneurons may improve, but also strengthening of corticospinal connections may explain the effects of FES in the long term.

Study objective

The main goal of this study is to evaluate the functional efficacy of the Actigait® system as a FES device, as well as its training effects with regard to (complex) walking. In addition, with regard to the training effects of FES, we intend to discriminate potential changes in the integrity of the corticospinal tract from more peripheral changes.

Study design

Patients will be informed about this study by their physiatrists and eligible patients will be invited to participate. An intake visit will be planned with the physiatrists of the department of rehabilitation in RUN-MC. If the response to external FES is not yet known, the patient*s response will be evaluated during a 4-week test period with external FES prior to inclusion. After 4 weeks, the Actigait system will be implanted in a 45-minutes neurosurgical procedure. Three weeks after surgery, the system will be set up and the patient can start its use.

The quality of both unobstructed and obstructed gait skills will be assessed. Furthermore, changes in corticospinal excitability as a result of FES will be determined by measuring MEPs in the leg muscles resulting from transcranial magnetic stimuli. Effects on both the gait ability and the corticospinal integrity will be evaluated at baseline (before implantation), at *short-term* (after a 2 weeks adaptation period), *middle-term* (8 weeks) and *long-term* (after 26 and 52 weeks of use). For each of these 5 evaluations, two visits will be scheduled at the mobility lab in the Radboud University Nijmegen - Medical Center (RUN-MC). In week 1, 2, 3, 5, 8 en 26 after the start with Actigait®, a telephone interview will be held to evaluate the extent of usage and the activities performed with Actigait. Finally, patients* satisfaction, social participation and physical ability will be assessed by means of questionnaires, and the activitation level by means of a pedometer. This will be assessed regarding their normal walking condition (which may include an AFO and/or shoe adaptation) and regarding Actigait®

Intervention

Implantation and usage of a 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 lead to nerve damage. In a prior study in RUN-MC, this complication occured due to a change in the the surgical procedure. The procedures have been adjusted and no further complications occured with the renewed procedures. Also in a prior study on the safety of the Actigait system by Burridge et al. (2007), in which the same surgical procedure was used as will be in the proposed study, no such events occurred.

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 18-70 years
- able to visit the academic hospital in Nijmegen on multiple occasions during a 15-months period
- positive response to an external FES system

Exclusion criteria

- severe cognitive deficits
- pregnancy
- psychological disorders (e.g. 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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	15-02-2011
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	implantable neuroprosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-11-2010
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	NL32665.091.10