The effect of the implantable two-channel peroneal nerve stimulator as a treatment in stroke patients with a drop foot in comparison with the conventional treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28906

Source
Nationaal Trial Register

Brief title
RCT PNS (peroneal nerve stimulation).

Health condition

Chronic stroke patients with a drop foot.

Sponsors and support

Source(s) of monetary or material Support: SENTER Internationaal

Intervention

Outcome measures

Primary outcome

Walking speed.

Secondary outcome

1. Endurance;

2. Spasticity;

3. EMG;

4. 3D-kinematics;

5. Quality of life questionnaires;

6. Activity monitoring;

7. Carry-over effect.

Study description

Background summary

Dropped foot is a condition found in several patient groups, including Multiple Sclerose, incomplete spinal cord injury and most notably, stroke.

Stroke is one of the most common disorders affecting the neuromuscular system.

The conventional management of dropped foot has been to use a rigid orthosis to maintain the ankle in a neutral position. This has major limitations as a treatment, being both uncomfortable and awkward to use and hence is often rejected by patients and therapists.

Currently, FES systems for the treatment of dropped foot are in clinical use in significant numbers.

Functional Electrical Stimulation (FES) is the artificial stimulation of muscles with the purpose of evoking a motor response.
Compared with the use of orthosis electrical stimulation has a number of advantages: it prevents muscle atrophy, the blood flow remains normal or even improves and it is cosmetically better accepted.

An implantable system was developed that stimulates the two branches of the peroneal nerve separately. Results from previous studies indicate that the system is safe to use, well liked by the patients, provides selectivity over moments at the ankle joint and increases both walking speed and endurance.

In the present study the additional value of the implantable stimulator in comparison with the conventional treatment will be examined by measuring different parameters.

Study objective

The FES group will show in comparison with the conventional therapy group:

1. increased gait speed (primary outcome);

2. increased endurance;

3. improved gait kinematics;

4. increased muscle activity level;

5. reduced spasticity;

6. positive effect on passive ROM;

7. reduced disability.

Study design

N/A

Intervention

Two-channel implantable peroneal nerve stimulator.

Contacts

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Eligibility criteria

Inclusion criteria

1. Dropped foot identified by an inability to achieve a normal heel strike during walking;

2. First hemiplegia of at least 6 months as a result of a CVA with a stable neurology;

3. Successful functional recovery after surface stimulation of the common peroneal nerve;

4. Subject is an outdoor walker;

5. Able to give informed consent.

Exclusion criteria

1. Age < 18 year;

2. Passive dorsiflexion of the ankle <5º with knee in extension;

3. Medical conditions limiting the function of walking other than CVA, i.e. neurological, rheumatic, cardio-vascular or systemic disorders (including Diabetes Mellitus);

4. Injury of n.peroneus or n.ischiadicus;

5. Not be able to don and doff the equipment;

6. Pregnancy.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2002
Enrollment:	29
Type:	Actual

Ethics review

Positive opinion

Date:	28-09-2005
Application type:	First submission

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
NTR-new	NL454
NTR-old	NTR494
Other	: 001
ISRCTN	ISRCTN75455247

Study results

Summary results
N/A