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.

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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....

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28906

Bron
Nationaal Trial Register

Verkorte titel
RCT PNS (peroneal nerve stimulation).

Aandoening

Chronic stroke patients with a drop foot.

Ondersteuning

Overige ondersteuning: SENTER Internationaal

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Walking speed.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Two-channel implantable peroneal nerve stimulator.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2002
Aantal proefpersonen:	29
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL454
NTR-old	NTR494
Ander register	: 001
ISRCTN	ISRCTN75455247

Resultaten

Samenvatting resultaten

N/A