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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

Submission date
27/01/2006

Registration date
27/01/2006

Last Edited
04/07/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001; NTR494

Study information

Scientific Title
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

Acronym
RCT PNS (peroneal nerve stimulation)

Study objectives
The functional electrical stimulation (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 range of movement (ROM)
7. Reduced disability

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dropfoot, stroke

Interventions
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, functional electrical stimulation (FES) systems for the treatment of dropped foot are in clinical use in significant numbers. 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 two-channel implantable peroneal nerve stimulator in comparison with the conventional treatment will be examined by measuring different parameters.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Walking speed

Secondary outcome measures
1. Endurance
2. Spasticity
3. EMG
4. 3D-kinematics
5. Quality of life questionnaires
6. Activity monitoring
7. Carry-over effect

Overall study start date
01/09/2002

Completion date
31/12/2005

Eligibility

Key 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 cerebrovascular accident (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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
29

Total final enrolment
29

Key exclusion criteria
1. Aged less than 18 years
2. Passive dorsiflexion of the ankle less than 5° 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

Date of first enrolment
01/09/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Roessingh Research and Development
Enschede
Netherlands
7500 AH

Sponsor information

Organisation
Roessingh Research and Development B.V. (The Netherlands)

Sponsor details

P.O. Box 310
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Sponsor type
Research organisation

Website
http://www.rrd.nl

ROR
https://ror.org/01dmjt679

Funder(s)

Funder type
Government

Funder Name
SENTER - A branch of the Dutch Ministry of Economic Affairs (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2007	04/07/2019	Yes	No