Ambulation performance in chronic stroke patients using an implanted drop foot stimulator

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

Summary

ID

NL-OMON32078

Source
ToetsingOnline

Brief title
AMPECS

Condition

- Central nervous system vascular disorders

Synonym
central motor neuron lesion

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ziekenhuisbudget

Intervention

Keyword: drop foot, functional stimulation, stroke

Outcome measures

Primary outcome

Primary outcome measures:

* Gait parameters: walking speed, gait symmetry, gait width, foot placement,cadence,gait fluency,

* Two minute walking test (Brooks 2001, Datta 1996)

* Functional gait performance: - outdoor circuit with different surface textures (Kölgen et al., 2002),

indoor participation circuit (Hemmen et al., 2007; Stevens et al., 2006; Ilmer et al., 2007)

- Family Qol & Stroke specific utlities.(see attachment)

- Generic quality of life: SF-36 (vd Zee et al., 1993)

Secondary outcome

Secondary outcome measures:

* * Functional health status: Functional Independence Measure (FIM) (Kidd et al., 1995)

* Anxiety and depression: HADS (Spinhoven et al., 1997)

Cognitive functioning: MMSE (Jackson et al., 2007)

* Functional health status,

. Functional independence measure (FIM)

* Credibility/expectancy questionnaire (CEQ) (Devilly & Borkovec, 2000)

Study description

Background summary

The incidence of cerebrovascular accidents (CVA) in the Netherlands is estimated to be 30.000 a year.(NHG-Standaard CVA , verhoeven et al 2004).Twenty percent die, 20% survive without neurological deficit and 60% have a partial recovery of which 50% (9000) have walking problems. (Bonita 1998) Early rehabilitation results in a better functional recuperation (Kwakkel 1999) 3/4 of the patients with a walking problem return to adequate functioning after 3 months (Kwakkel 1999, Jorgensen 1995, a, b) Approximately 30% do not recuperate (Wade 1987). The incidence of CVA with the increasing age of the population will result in 35000 CVA cases a year in 2015. The LMR data give an incidence of 44.320 for the year 2006.
Hoensbroek is the largest rehabilitation center in Limburg with connections to all large hospitals. A working group with participants from all departments and focused on this project covers the whole population of Limburg. (1.2 milj)

Study objective

The aim is to convince the rehabilitation community that drop foot after stroke can be functionally corrected which increases significantly quality of life. The information will be spread through rehabilitation centers targetting rehab physicians, physiotherapists in the Netherlands. We now approached all rehabilitation department and nursing houses in the region. They are committed to the project and a working group is created to update and train participants. If we are successful the programm will be dissiminated through the country in a restricted number of rehabilitation centers.

Study design

Piolt study related to a larger study which belongs to the cost effective area as defined by ZonMW. Proposal is submitted in september.

Intervention

Surgical intervention of an inerve stimulating device which consists of 2 parts. The electrodes are fixed on the nerve and the receiver is placed subcutaneously. The pulse generator is placed on the skin. This is a minor surgery. However as it concerns an implant care must be taken to avoid infection. Antibiotics are given for 24 h.

Study burden and risks

The disease is an upper motor neuron deficit with a dropfoot as major clinical impairment. The condition
is found in CVA, MS and spinal cord lesions. This study focuses on CVA patients as this group is the
largest.
A cerebrovascular accident accompanied by a hemiparesis may apart from the cognitive impact reduce
the mobility of the patient. The walking imbalance restricts the patient activities and increases the risk of
falling resulting in a important reduction of the quality of life. Usual therapy consists in stabilization of the
walking problem by physiotherapy and/or orthosis. This does not eliminate abnormal walking. Important
amelioration may be expected from an active correction of the imbalance by electrical stimulation of the
involved nerves.
Risks for the patients are comparable to all other surgical minor intervention where a small device has to be implanted. Comparable with a neurostimulator or pacemaker.

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

* age >< = 18 years;
* first ever supratentorial stroke with persistent neurological deficit
* post-stroke time between 6 and 24 months;
* Diagnosis and stroke severity
* BARTHEL INDEX * 15
*
* clinically diagnosed central paresis of the leg;
* drop foot, i.e. inability to achieve a normal heel strike during walking
* balance and gait-related criteria: subject is an outdoor walker:
* Berg Balance score 48/56;
* Rivermead mobility index 11/15.
* strength MRC grade * 3 at entry into the study
* no injury to peroneal nerves and sciatic nerve
* (EMG to exclude peripheral nerve lesion,
* trial stimulation to evaluate dorsiflexion and eversion of the foot)
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Exclusion criteria

* pacemaker
* any medical condition that would exclude the use of a surgical procedure or anaesthetic
* pregnancy
* inability to read or understand Dutch or receptive aphasia?
* no informed consent

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL20279.096.07