Gait training assisted by dual-channel functional electrical stimulation in early stroke rehabilitation: a proof-of-principle RCT

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To investigate the feasibility of a 10 week (maximum) gait training with DFES in rehabilitation starting in the sub-acute phase after stroke and the initial efficacy on the recovery of spatiotemporal parameters, gait kinetics and kinematics,...

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

Summary

ID

NL-OMON45202

Source
ToetsingOnline

Brief title
GAFESS (Gait training Assisted by FES in Stroke rehabilitation)

Condition

- Central nervous system vascular disorders

Synonym
Cerebral Vascular Accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electric stimulation, Gait disorders, neurological, Rehabilitation, Stroke

Outcome measures

Primary outcome

Stride length symmetry ratio (spatial parameter) assessed with the SGAS.

Secondary outcome

Other spatiotemporal parameters (timing stance and swing phase, double support time, swing:stance time, ratios, step length, gait speed), EMG, functional walking ability, balance and patient satisfaction.

Measurement properties of the SGAS: concurrent validity and inter- and intra-rater reliability.

Study description

Background summary

Many patients after stroke suffer from reduced walking ability because of pareses of lower extremity muscles. Functional electrical stimulation (FES) has been used to improve walking ability but evidence is limited to peroneal FES, which only stimulates the distal part of the lower extremity. A recently developed device, the NESS L300* Plus, is a lower extremity dual-channel FES (DFES) system, activating proximal as well as distal muscle groups of the lower extremity. Evidence for effectiveness in stroke rehabilitation is lacking. The use of DFES in the early gait rehabilitation after stroke may enhance gait efficiency.

Study objective

To investigate the feasibility of a 10 week (maximum) gait training with DFES in rehabilitation starting in the sub-acute phase after stroke and the initial efficacy on the recovery of spatiotemporal parameters, gait kinetics and kinematics, functional ambulation, walking ability and mobility. And to assess

validity and reliability of the spatiotemporal gait analysis system (SGAS).

Study design

A proof-of-principle randomized clinical trial and a cross-sectional study.

Intervention

Additional to standard gait training during inpatient stroke rehabilitation, subjects in the intervention group receive DFES-assisted gait training for one 30-minute session each workday, during maximal 10 weeks.

Study burden and risks

The burden related to study participation of the patients consists of time and effort invested in the assessments at baseline, every two weeks during the intervention period and the two follow up assessments. Subjects in the intervention group may perceive some discomfort from electrical stimulation but this will be transient and subjects will probably adapt to this. A risk of participation is skin problems at the site of the stimulation electrodes from the stimulation. Therefore, the intervention starts with an adaptation period. The study burden for the healthy subjects consists of repeated walking assessments during a single visit.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
- clinical diagnosis of stroke (diagnostic criteria according to the World Health Organisation definition);
- 14-31 days since stroke onset;
- age between 18 and 80 years old;
- referred to inpatient rehabilitation;
- medically stable and able to follow an intensive rehabilitation program;
- indication for gait training;
- sufficient power to stand in parallel bars with or without physical assistance;
- passive range of motion (PROM) ankle dorsiflexion of at least 0 degrees at full knee extension.;Healthy subjects:
- age between 18 and 80 years old;
- healthy (self-reported); and
- no gait deficits due to diagnosed medical conditions.

Exclusion criteria

Patients:
- subarachnoid hemorrhage;
- stroke in the cerebellum or brain stem;
- pre-existing lower extremity deficits or any other medical co morbidities that interfere significantly with gait;
- severe cognitive problems or aphasia with severely impaired comprehension of test instructions;
- medical conditions that prevents participation or will lead to inability to comply with the protocol (e.g., congestive heart failure, patient receiving chemotherapy, uncontrolled epilepsy, pregnancy, depression or a psychotic disorder, etc.);
- a demand-type cardiac pacemaker, defibrillator or any electrical implant;
- a metallic implant at the affected lower extremity; or
- a present or suspected cancerous lesion at the affected lower extremity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2014
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	NESS L300 Plus
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2016
Application type:	Amendment

Review commission: METC Amsterdam UMC

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
Other	19364
CCMO	NL50002.018.14