Design and evaluation of multichannel stimulation algorithms to support hand opening during functional reach-to-grasp movements in stroke patients

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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-OMON38359

Source ToetsingOnline

Brief title Electrical stimulation for post stroke handopening

Condition

Central nervous system vascular disorders

Synonym CVA, stroke

Research involving Human

Sponsors and support

Primary sponsor: Roessingh Research & Development

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Source(s) of monetary or material Support: Euregio subsidie via de Europese Unie (Interreg IV A)

Intervention

Keyword: electrical stimulation, electromyography, hand opening, stroke

Outcome measures

Primary outcome

The main study parameter of the present experiment is the Box and Block test

which measures hand function of stroke patients. This functional measure is

used to evaluate the influence of different types of electrical stimulation on

functional hand opening.

Secondary outcome

Secondary study parameters are muscle activation patterns (MAP) measured with

electromyography and kinematics during reach-to-grasp movements.

Study description

Background summary

The majority of stroke patients have to cope with impaired arm and hand function after a stroke. Post stroke rehabilitation training aims to regain (partly) lost functions by stimulation of restoration or promoting compensational strategies, in order to increase the level of independence. During rehabilitation training movements are practiced preferably with high intensity, in a task-oriented way, with an active contribution of the stroke survivor in a motivating environment. An effective training modality that is commonly applied in post stroke upper extremity rehabilitation training is arm support by means of gravity compensation. In order to increase functional abilities of the affected arm, hand function should also be trained. A promising technique to train hand function, or more specifically hand opening, after stroke is electrical stimulation of wrist and finger extensors and thumb abductors/extensors.

Study objective

The primary objective of the present study is to study influence of different types of electrical stimulation on functional hand opening. The secondary objective of the study is to gain more insight in muscle activation patterns and kinematics during functional reach-to-grasp movements.

Study design

The study has a cross-sectional design, with one measurement session (T1) for healthy elderly and two sessions (T1 and T2, spaced approximately 3 months apart) for stroke patients.

Intervention

During the T2 experiment, stroke survivors will perform the Box and Block Test (BBT) in three conditions:

- 1. Without electrical stimulation
- 2. With single channel electrical stimulation to support hand opening.
- 3. With multi channel electrical stimulation to support hand opening.

Study burden and risks

The risks for the subjects are limited to a minimum, since the movement tasks represent functional and familiar arm movements and are performed only within the scope of the subject*s ability while he/she is seated. In addition, the measurements used in this study (EMG, kinematics, functional scales) are all noninvasive and involve no risks to the patients in any way. During the T2 measurement stroke patients receive electrical stimulation applied by surface electrodes. During long term electrical stimulation skin irritation is possible. The risk for skin irritation is minimized by stimulation with as low as possible amplitudes and minimizing the time during which the stimulator is active.

Participation of a subject in this experiment has no direct benefit for him/her, other than expanding knowledge about underlying mechanisms of motor control of the arm and hand and aiding in development of sophisticated multichannel electrical stimulation algorithms.

Contacts

Public

Roessingh Research & Development

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Scientific Roessingh Research & Development

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Inclusion criteria for stroke patients are:

1. a history of a single unilateral stroke in the medial cerebral artery (MCA) region resulting in single-sided hemiparesis.

2. the onset of the stroke was more than six weeks ago

3. the ability to voluntarily generate 20 degrees excursions in the plane of elevation (horizontal ab-/adduction) and elevation angle (ab-/adduction, ante-/retroflexion) of the shoulder joint.

4. the ability to voluntarily generate an excursion of 20 degrees of elbow flexion/extension,

5. the ability to voluntarily extend the wrist 10 degrees from neutral flexion/extension

6. adequate cognitive function to understand the experiments, follow instructions, and give feedback to the researchers.;Inclusion criteria for healthy elderly are:

1. ability to decide whether or not to participate in the experiment and sign an informed consent.

Exclusion criteria

Exclusion criteria for both stroke patients and healthy elderly are:

- 1. a fixed contracture deformity in the affected upper limb was present
- 2. pain as a limiting factor for the subject's active range of motion
- 3. age below 40 years

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Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2011
Enrollment:	40
Туре:	Actual

Medical products/devices used

Generic name:	Electrical stimulation
Registration:	No

Ethics review

Approved WMO	11 02 2011
Date:	11-02-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	06-03-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28137 Source: NTR Title:

In other registers

Register CCMO OMON ID NL34868.044.10 NL-OMON28137