Clinimetric properties of the SMT.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25852

Source
Nationaal Trial Register

Health condition

Spasticity of stroke patients
Spasticiteit bij CVA patienten

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: Roessingh Research and Development

Intervention

Outcome measures

Primary outcome

RMS of the EMG, Force and angular velocity.

Secondary outcome

1. PRPM: An ordinal scale derived from the Asworth scale;

2. VAS scale.

Study description

Background summary

Rationale:

Spasticity is a phenomenon which can occur after an upper motor neuron (UMN) lesion. Although the cause of spasticity is not completely understood, the current idea is that it is caused by a net loss of inhibition of spinal reflexes. Spasticity treatment is important for an optimal rehabilitation, but nowadays there are no objective measurement tools available yet. In clinical settings, the Ashworth scale is still used, although studies have shown that this measurement tool is neither sufficiently valid nor reliable. Therefore a potentially objective measurement tool is developed at Roessingh Research & Development. The aim of this study is to determine the clinimetric properties of the Spasticity Measurement Tool (SMT).

Objective:

The primary objective of this study is to define and evaluate the clinimetric properties of the SMT in terms of validity and reliability.

Study design:

The study has a cross-sectional design.

Study population:

16 stroke patients with chronic spasticity and 16 healthy subjects who are age and sex matched with the patient group.

Main study parameters/endpoints:

The main study parameters in this study are derived from the surface EMG, force and angle.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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 non-invasive and involve no risks to the patients in any way. Participation of a subject in this experiment has no direct benefit for him/her, other than expanding knowledge about the clinimetric properties of the SMT measurement tool.

Study objective

N/A

Study design

Healthy subjects will be measured once, patients with spasticity after a stroke will be measured twice (with one week between the measurements).

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for stroke patients are:

1. A history of a single unilateral stroke resulting in hemiparesis with a slight to moderate spasticity in the lower arm;

2. The onset of the stroke was more than three months ago;

3. The patient is above 18 years;

4. Adequate cognitive functions to understand the experiments, follow instructions, and give feedback to the researchers.

Inclusion criteria for healthy subjects are:

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

2. Age and sex matched to the patient group.

Exclusion criteria

Exclusion criteria for both stroke patients and healthy subjects are:

1. A fixed contracture deformity in the (affected) upper limb was present;

2. Suffering of any medical, psychological or cognitive impairment which may have compromised safety or the ability to comply with the protocol.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2011
Enrollment:	32
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36210
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2693
NTR-old	NTR2823
CCMO	NL35925.044.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36210

Study results

Summary results

N/A