Clinimetric properties of the Spasticity Measurement Tool, an objective measurement instrument to define spasticity in stroke patients

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON36210

Source
ToetsingOnline

Brief title
Clinimetric properties of the SMT

Condition

- Movement disorders (incl parkinsonism)

Synonym
'muscle spasm', spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Roessingh Research & Development
Source(s) of monetary or material Support: Roessingh research & Development: Cluster

NINA: WOR spasticiteit

Intervention

Keyword: EMG, Measurement, Objective, Spasticity

Outcome measures

Primary outcome

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

and angle.

Secondary outcome

The results of the clinical scales that are used (Perceived Resistance to

Passive Movement (PRPM) an the VAS scale)

Study description

Background summary

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).

Study 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 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. 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.

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

patients:
1. A history of a single unilateral stroke resulting in hemiparesis with 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.
5. Ability to decide whether or not to participate in the experiment and sign an informed consent.;Healthy subjects:
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

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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2011
Enrollment:	32

Type:	Actual

Ethics review

Approved WMO Date:	19-04-2011
Application type:	First submission
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: 25852
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCTnummervolgt,trialgeregistreerdbijwww.trialregister.nl
CCMO	NL35925.044.11
OMON	NL-OMON25852