Instrumented spasticity assessment for use in clinical practice

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

Summary

ID

NL-OMON44548

Source
ToetsingOnline

Brief title
Instrumented spasticity assessment

Condition

- Movement disorders (incl parkinsonism)

Synonym
spasticity; increased muscle tension

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Innovation fund Rijndam

Intervention

Keyword: Instrumented, Sensor, Spasticity

Outcome measures

Primary outcome

Inter rater reliability of two instrumented spasticity scales (Modified

Ashworth Scale, Modified Tardieu Scale).

Secondary outcome

Agreement between the instrumented and non-instrumented spasticity measurements.

Algorithms to distinguish between neural and non-neural stiffness.

Algorithms to evaluate other relevant clinical symptoms associated with

spasticity.

Study description

Background summary

Spasticity is a common phenomenon in upper motor neuron disorders. Spasticity impedes voluntary movements and can lead to muscle shortening and pain. In clinical practice, the severity of spasticity is usually determined by subjective scales. It has been shown that both the intra and inter rater reliability of these scales is moderate to bad. This is probably due to the difference in experience between testers and the related manner in which the tests are performed. An instrumented measurement using sensor technology could improve the reliability and value for clinical decision making of these scales.

Study objective

The main purpose of this research is to assess the interrater reliability (3 raters) of an instrumented clinical spasticity measurement. Also, the agreement will be determined between the instrumented and non-instrumented spasticity measurement. Secondary goals are the development of algorithms to distinguish between neural and nonneural stiffness and to objectify other relevant clinical symptoms related to spasticity, such as clonus and catch intensity.

Study design

This study has a cross-sectional research design. On one day, participants will be tested by three different physicians/therapists.

Study burden and risks

Participants in the study will have a single 45-minute visit in the Erasmus MC or Rijndam rehabilitation center. During that visit, 3 doctors / therapists will do an instrumented Modified Ashworth Scale and Tardieu Scale. Since these scales have been used in clinical practice for a long time, these measurements provide little risk to the participants. The stretching of the spastic muscle may feel uncomfortable in the final position, and the day after the measurement, muscle soreness can be felt.

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 clinically diagnosed with spasticity (MAS > 0)
- At least 18 years of age
- Suffering from spasticity in either the elbow flexors or extensors, knee flexors or extensors, or ankle plantar flexors.

Exclusion criteria

- Having undergone any surgical treatment that influences passive and/or active joint motion.
- Presence of disturbing neurological signs like dystonia, rigidity and tremors.
- Not able to read and/or understand the patient information letter.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-09-2017
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62487.078.17