ISA: evaluation of instrumented spasticity assessment in children and adults with spastic paresis

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The primary objectives of this study are (a) to evaluate reliability and precision of an instrumented spasticity assessment device (ISA) in children with cerebral palsy and adults with spastic paresis (MS and stroke patients) and (b) to validate ISA...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43564

Source
ToetsingOnline

Brief title
ISA: instrumented spasticity assessment

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
muscle stiffness, spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Fonds Nuts Ohra en Phelps Stichting voor

spastici

Intervention

Keyword: measurement, muscles, spasticity

Outcome measures

Primary outcome

Five muscle groups of the lower extremities will be tested with ISA: 1) gastrocnemius; 2) soleus; 3) hamstrings; 4) rectus femoris; 5) hip adductors .
In addition, two muscle groups of the upper extremities will be tested with ISA: 6) elbow flexors; 7) wrist flexors. Patient positioning and movement direction of slow and fast passive muscle stretch will be based on accepted clinical protocols.
In adults, all muscle groups will be tested. The children will be divided in 2 groups (upper and lower extremity testing each maximal two joints) to limit the time of the assessment.

Primary outcome parameters measured by ISA are work [J] (area under the power-time curve) and muscle activity (root mean square (RMS) EMG [uV]) for both slow and fast stretch, the determine the non-neura; and neural contribution to hyper-resistance.

To test the intra- and inter-rater reliability and measurement precision, intraclass correlation coefficient (ICC), standard error of measurement (SEM) and smallest detectable difference (SDD) will be calculated for each of the outcome parameters.

To test validity, the non-neural and neural outcome parameters will be correlated to the SPAT-scores (0-4 for catch), muscle tone (-1,0,1) and Ashworth scale (0-4).

Secondary outcome

Secondary outcome measures are maximal velocity of performance (Vmax [deg/s]), range of motion [deg], and stiffness [Nm/deg] for slow stretches to determine the non-neural contribution. To determine the neural contributions in the fast stretch secondary outcome measures are: maximal velocity of performance (Vmax [deg/s]), joint angle of catch [deg], angle of EMG threshold [deg], and intensity of catch (power [W]; torque times angular velocity).

Further secondary outcome parameters are the usability of the instrument (including hard- and software parts) evaluated by a modified version of the System Usability Scale (SUS) and the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST), and the patient-friendliness, evaluated by a modified version of the Orthotics and Prosthetics Users* Survey Satisfaction with Devices and Services (OPUS-SDS) and the QUEST.

Study description

Background summary

Spasticity is a clinical phenomenon that is frequently present in neurological diseases, such as cerebral palsy (CP), multiple sclerosis (MS) and stroke. It is defined as a velocity dependent stretch hyperreflexia and is one of the contributors to hyper-resistance felt during clinical examination (i.e. passive slow and fast stretch of a muscle).
Several physical examination tests have been developed to assess spasticity in

clinical practice, using passive muscle stretches at one or more velocities and determining the angle of catch, defined as sudden resistance in the range of motion due to fast stretch. However, in these tests it is difficult to discriminate spasticity from other causes of hyper-resistance that is felt during the physical examination. Furthermore, standardisation, quantification and objectivity is lacking in these tests.
Therefore, we developed a measurement instrument for precise quantification of hyper-resistance and its underlying components (non-neural and neural) in daily clinical practice, based on internationally-accepted clinical protocols: the ISA-device (which stands for: instrumented spasticity assessment), measuring joint angle, angular velocity, muscle activity (electromyography (EMG)) and applied torque.
Prior to application, the newly developed measurement instrument needs to be tested for its clinometric properties, such as intra- and inter-rater reliability, measurement precision and validity. Furthermore, the usability for clinicians/examiners as well as patient friendliness need to be tested.

Study objective

The primary objectives of this study are
(a) to evaluate reliability and precision of an instrumented spasticity assessment device (ISA) in children with cerebral palsy and adults with spastic paresis (MS and stroke patients) and
(b) to validate ISA in children with cerebral palsy and adults with spastic paresis by comparing this (concurrent validity) to the current clinical standard (Spasticity test (SPAT), muscle tone and Ashworth scale (only in adults)).

The secondary objectives are
(c) to evaluate usability of this instrument in daily clinical practice for the performing clinicians/examiners and
(d) patient friendliness of ISA.

Study design

Observational study with a intra- and inter-rater design, including 2 examiners

Study burden and risks

The burden and risks for the participants of this study are minimal.
ISA may optimize the clinical decision-making of spasticity treatment in relation to the aetiology, such as the dose-effect of spasticity reducing medication. The subjects however will not have a direct benefit by participating in the study since first the clinometric properties of the instrument need to be evaluated and no intervention will yet be applied based on outcome of the ISA.

The ISA device is specifically designed for clinical application in children and also applicable for adults. Former research with spasticity tests and with a previous prototype with children showed no risks.
The measurements are non-invasive and passive. The patient will be instructed to completely relax.
During the tests, little fatigue, uncomfortable feeling and/or pain could occur, however due to the nature of the tests (passive) and sufficient resting periods between the tests the chance this will happen is limited.
The sensors and materials on the skin exist of skin-friendly material to avoid any skin irritation.
After the measurement, a temporary uncomfortable feeling or pain might be experienced in the muscle due to the muscle stretch. However, this will soon disappear and does not cause any damage.
Patients will also be made aware that they are free to withdraw from the study at any time without giving a reason and with no further consequences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Clinically established spasticity
- Children: GMFCS I-IV
- Age: 6-18y for the children
- Age: 18-70y for the adults
- Able to participate in the experiment for 1.5 hours.

Exclusion criteria

- unable to follow instruction
- patients who are already included in any other experimental research study
- Concomitant orthopedic disorders such as rheumatoid arthritis, osteoarthritis
- Concomitant neurological disorders
- Baclofen pump
- Change of (spasmolytic) medication in the past 4 weeks

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	25-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2017
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
CCMO	NL54698.029.15