Evaluating the value of neuromechanical assessment in spasticity treatment

Published: 02-03-2023
Last updated: 10-01-2025

1. Evaluate the relation between pretreatment muscle weaknesses, spasticity, abnormal synergies, and changes in viscoelastic joint properties on the one hand, and changes in upper extremity spasticity following treatment on the other hand in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON53571

Source
ToetsingOnline

Brief title
ASSIST

Condition

- Neurological disorders congenital
- Central nervous system vascular disorders

Synonym
cerebral paresis, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,NWO VENI,Hankamp Rehab

Intervention

Keyword: Diagnostics, Paretic arm, Spasticity

Outcome measures

Primary outcome

1. Relation between pre-treatment muscle weakness, spasticity, abnormal synergies, and changes in viscoelastic joint properties and treatment outcome quantified by change spasticity with a multivariable regression analysis, correcting for several patient characteristics.

2. Responsiveness to treatment, quantified as the standardized mean difference, of muscle weakness, spasticity, synergy, and viscoelasticity of the elbow measured with the SEP.

Secondary outcome

N.A.

Study description

Background summary

Impaired upper extremity motor function is a common problem in patients who suffer an upper motor neuron lesion (e.g., a stroke or cerebral palsy (CP)), which has a major impact on their quality of life. Clinical signs of impaired upper extremity function include muscle weaknesses, spasticity, abnormal synergies, and changes in viscoelastic joint properties. Current clinical assessments to study these signs include the Modified Ashworth scale, Tardieu scale, Brunnstrom Fugl-Meyer scale, and Test of Arm Selective Control. During a previous project (NL64660.078.18), we developed a reliable and valid neuromechanical assessment protocol to quantify the elbow's muscle weakness, spasticity, synergy, and viscoelasticity using a single robotic device, the Shoulder Elbow Perturbator (SEP). As a next step, we want to investigate if the outcome SEP scores obtained at baseline relate to the effect of non-pharmacological, pharmacological, and surgical treatment options for upper extremity spasticity in patients with upper motor neuron lesions. In addition,

we wish to investigate the responsiveness to clinical change of the neuromechanical assessment outcome measures.

Study objective

1. Evaluate the relation between pretreatment muscle weaknesses, spasticity, abnormal synergies, and changes in viscoelastic joint properties on the one hand, and changes in upper extremity spasticity following treatment on the other hand in patients with upper motor neuron lesions electing to undergo treatment for upper extremity spasticity.
2. Investigate the responsiveness to treatment of the scores (muscle weakness, spasticity, synergy, and viscoelasticity of the elbow), measured with the SEP.

Study design

Longitudinal observational study. We will extend the routine outcome measures performed during the spasticity outpatient clinic in Rijndam Rehabilitation, ErasmusMC or Amsterdam UMC (locatie VUmc) with additional measurements with the SEP. Patients are currently routinely measured before a treatment decision is made as part of clinical decision-making. Measurements will be performed before treatment and 4-6 weeks after treatment.

Study burden and risks

The SEP is a non-invasive robotic device developed by Hankamp (Enschede, the Netherlands) that imposes forces and displacements to the participants' forearm. The device has several safety measures, in hard- and software, that are explained in the IMDD file. The neuromechanical assessment protocol using the SEP takes no longer than 45 minutes and has been previously developed as part of protocol number NL64660.078.18. During the study, there will be no direct benefits for the participants. However, the results of the current project can presumably facilitate treatment decision making in the long term for these target populations.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Visiting the outpatient clinic in Rijndam Rehabilitation Center, Erasmus MC, or Amsterdam UMC (location VUmc) to seek treatment of spasticity of the upper extremity.
- >=18 years;
- Minimal passive range of motion (PROM) in shoulder joint: 0-80° abduction, 0-45° anterior flexion.
- At least some volitional control of elbow flexion and extension;
- Having given written informed consent prior to undertaking any study-related procedures.

Exclusion criteria

- Inability to understand instructions (for example due to intellectual impairment);
- History of pre-existing neuromusculoskeletal disorders that would influence the upper extremity function (e.g., presence of a prosthetics shoulder, other neurological condition which might affect upper extremity function, surgery/specific treatment <= 6 months);
- Damaged skin of the arm that interferes with the measurement set-up and/or has negative influence for the participants;
- Contractures present at the upper limb that limit possibility to be fitted in the SEP.

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):	01-02-2023
Enrollment:	150
Type:	Anticipated

Medical products/devices used

Generic name:	Shoulder Elbow Perturbator
Registration:	No

Ethics review

Approved WMO Date:	02-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	06-03-2024
Application type:	Amendment
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	NL80419.078.22