Quantifying paretic upper limb impairment in stroke and cerebral palsy

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To develop a feasible assessment protocol to quantify the impaired upper extremity function in terms of muscle weakness, spasticity, synergy and viscoelastic properties around the elbow.To evaluate the reliability (test-retest, measurement error)...

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

Summary

ID

NL-OMON48692

Source
ToetsingOnline

Brief title
Re-Arm

Condition

- Neurological disorders congenital
- Central nervous system vascular disorders

Synonym
Stroke; Cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: TKI-LSH (Match) Health-Holland,Hankamp b.v.

Intervention

Keyword: Cerebral palsy, Paretic arm, Spasticity, Stroke

Outcome measures

Primary outcome

The main study parameters are muscle weakness, spasticity, abnormal synergy and changed viscoelastic properties of the upper extremity, as measured with the Shoulder-Elbow Perturbation (SEP).

Secondary outcome

The secondary study parameters are spasticity and abnormal synergy as measured with clinical assessment tools.

Spasticity:

In stroke patients and adults with CP: Tardieu scale.

Synergy:

In stroke patients: Brunnström Fugl-Meyer (BFM) of the upper extremity;

In adults with CP: Test of Arm Selective Control (TASC).

Study description

Background summary

Disability in upper extremity function, due to sensorimotor deficits and other deficits, is a common problem for patients that suffered from a stroke and adults with cerebral palsy (CP). This problem can lead to restricted mobility of the upper extremity, resulting in an impact on the quality of life [1]. Clinical signs of impaired upper extremity function are muscle weaknesses due to paresis or paralysis, abnormal reflex activity (spasticity), loss of independent joint control (abnormal synergies) and changes in viscoelastic properties (joint stiffness). Current clinical assessments to study these signs

include the Modified Ashworth scale and the Brunnstrom Fugl-Meyer scale. However, such clinical assessments have limitations, such as a high observer variability [2]. In order to improve treatment outcomes of upper extremity function interventions, accurate diagnosis of the explanatory deficits is needed. Previous studies already investigated assessment protocols to distinguish some clinical signs/parameters with a neuromechanical model in combination with a robot. To that end, a more comprehensive neuromechanical assessment to distinguish all four clinical signs, might provide better diagnosis. A robot device, combined with a scientific model, can presumably identify and quantify the contribution of muscle weakness, abnormal reflex activity, loss of independent joint control and changes in viscoelastic properties to upper extremity impairment.

Study objective

To develop a feasible assessment protocol to quantify the impaired upper extremity function in terms of muscle weakness, spasticity, synergy and viscoelastic properties around the elbow.
To evaluate the reliability (test-retest, measurement error) and construct validity of the impaired upper extremity function parameters in chronic stroke patients and adults with CP.

Study design

Two cross-sectional exploratory studies will be performed at Erasmus MC and Rijndam Rehabilitation Center, The Netherlands.

Study burden and risks

This study is a non-invasive diagnostic study. During the study there will be no direct benefits for the participants. However, results of the current project can presumably facilitate treatment evaluation, treatment efficiency and treatment policy in the long-term for these target populations. In this study, a robot-arm device (SEP) developed by Hankamp (Enschede, the Netherlands) will be used. The SEP imposes a force on the forearm of the participants and measures relevant outcome parameters, which will be analyzed using neuromuscular models. The device has several safety measures that are explained in the IMDD file. Study participants will receive a SEP assessment that takes up to 60 minutes and next to clinical measurements (Tardieu scale and BMF/TASC).

Measurements can be experienced intensively for the affected arm because the SEP-assessment will take up to an hour. In total 6 assessments will be measured: 3 active measurements with the SEP-device, 1 passive measurement with the SEP device, 1 active clinical assessment, and 1 passive clinical assessment. During an assessment, 1 minute rest will be given between each

repetition and 5 minutes between assessments.
Patients will come to the hospital on different occasions:
For the first objective, the participants will come ones to the Erasmus MC.
For the second objective, the participants will come twice to the Erasmus MC (± 2 hours per visit).

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

- *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.;In addition, the following inclusion criteria apply for stroke patients:
- Patients need to have an unilateral upper extremity impairment;
- Chronic (> 6 months) patients.
In addition, the following inclusion criteria apply for adults with CP:
- Adults with CP need to have an upper extremity impairment;
- Spastic unilateral or spastic bilateral adults with CP.

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);
- Damage skin of the arm that interferes with the measurement set-up and/or has negative influence for the participants;
- Hemiplegic shoulder pain;
- Patients with fixed contractures in the upper extremity that hinder the experimental setup.
- Intellectual impairment, or psychiatric disorder that hinders understanding measurement instructions. ;In addition, the following exclusion criteria apply for adults with CP:
Adults with very severe motor disorders: a level V on the gross motor function classification system (GMFCS) and/or a level V on the manual ability classification system (MACS).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2019
Enrollment:	115
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-03-2019
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	NL64660.078.18