Non-invasive assessment of wrist flexion deformity in Cerebral Palsy and stroke

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To develop and validate a biomechanical measurement protocol that can assess wrist flexion deformity resulting from a UMN lesion.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30960

Source
ToetsingOnline

Brief title
Flexion deformity assessment

Condition

- Central nervous system vascular disorders

Synonym
Cerebral Palsy, Spastic paresis, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CP, Flexion Deformity, Spasticity, Stroke, Wrist

Outcome measures

Primary outcome

Location of the optimal length and passive stiffness curve of the flexor muscles and passive stiffness under high frequency perturbations; location of the optimal length and passive stiffness curve of the extensor muscles; active stiffness during constant activity for both muscle groups; inertia of hand, viscosity of wrist joint under high frequency perturbations.

Secondary outcome

Passive and active range of motion of the wrist joint, neutral position of the wrist, maximum voluntary contraction, Zancolli score, Ashworth score, Tardieu score, selected tendon reflex tests

Study description

Background summary

Upper Motor Neuron (UMN) lesions such as stroke or Cerebral Palsy often result in increased muscle tone, which in a number of cases leads to a flexion deformity in mostly distal joints, such as the wrist. Causes of the deformity may be either active/hypertonic (=hypertonic force imbalance) or passive/structural (=contracture formation). This difference is difficult to make clinically, but of paramount importance as the corresponding type of treatment is fundamentally different: either muscular tone is relieved by application of e.g. botulinum toxin, or the muscles/tendons are surgically lengthened. To date, reliable assessment can only be made during actual surgery. This radical, cost ineffective and time-consuming step in the process of therapy can become unnecessary when a non-invasive biomechanical measurement protocol is developed that can assess the affected joint. Most prone to contracture formation are Cerebral Palsy patients, since their bodies are still growing while motor abnormalities impair functionality.
Objective. To develop and validate a biomechanical measurement protocol that can assess wrist flexion deformity resulting from a UMN lesion.

Study objective

To develop and validate a biomechanical measurement protocol that can assess wrist flexion deformity resulting from a UMN lesion.

Study design

Case control; measurement of passive and active components of the force-length relation of involved muscles by measuring torque-angle relations and isometric force production under specified muscle activity, throughout the range of motion (ROM) of the wrist. Measurement of wrist joint impedance by applying perturbations and using linear system identification techniques to estimate intrinsic parameters

Study burden and risks

Measurements will be performed only once. Measurements take in total about 1 1/2 hours including instruction, mounting and demounting etc. The actual measuring time is small compared to the total session time. Measurements are performed at the Laboratory of Movement Analysis of the LUMC, where there is ample experience with the kind of measurements that comprise the present application. During the measurements, a technician as well as a physician will be present.

No side effects have been reported. Risks of serious side effects or complications of the measurements are regarded to be minimal. Security measures to prevent the wrist robot from working outside the prescribed positional ranges include software as well as hardware (blocks) embedded limits. The experiments can be stopped in case of emergency at any time by subject or experimenter by the presence of emergency buttons.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Cerebral Palsy patients
Inclusion criteria
• Young patients with motor disorders resulting from Cerebral Palsy, that have an abnormal wrist posture, i.e. showing a spontaneous flexion deformity of more than 30°
• Age between 12 and 18 years ;Stroke patients
Inclusion criteria
• Patients in the subacute to chronic stage after stroke who have developed a wrist flexion deformity, i.e. showing a wrist flexion angle of more than 30° at rest.;Control subjects
Inclusion criteria
• Age- (within one year deviation per patient), sex-matched.
• Predominantly healthy.

Exclusion criteria

Exclusion criteria CP
• A history of confounding morbidity around the wrist, e.g. fractures.
• Restricted vision (< 0.5)
• Loss of sensibility of the hand, preventing the patient from delivering the required task performance.
• Cognitive impairments preventing the patient from understanding the instructions required for the task that has to be performed.
• Other severe co- morbidity preventing patients from delivering the required task performance.
• Previous surgery on the wrist/ lower arm;Exclusion criteria stroke
• The same as for the CP patient group;Exclusion criteria control subjects

• History of previous or current neurological disorders of central origin or peripheral origin, e.g. Parkinson, Multiple Sclerosis, Stroke, nerve lesions, CRPS, plexus brachalis lesions etc.
• A history of confounding morbidity around the wrist, e.g. fractures..
• Restricted vision preventing subject from delivering the required task performance.
• Loss of sensibility of wrist, preventing from delivering the required task performance.
• Cognitive impairments preventing the subject from understanding the instructions required for the task that has to be performed.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18926.058.07