Tissue- and reflex torque through ramp-and-hold ankle rotations: understanding and quantifying spasticity in cerebral palsy

Published: 06-08-2010
Last updated: 18-07-2024

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

Summary

ID

NL-OMON34272

Source
ToetsingOnline

Brief title
Tissue- and reflex torque in cerebral palsy

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cerebral palsy, spastic paresis

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: Cerebral Palsy, quantification, Spasticity, System Identification and Neuromuscular Modelling (SIPE)

Outcome measures

Primary outcome

Ankle stiffness (Nm/rad), viscosity (Nms/rad) and reflex activity (Nm/rad)

Secondary outcome

SPAT and AS scores

Study description

Background summary

Cerebral Palsy is a perinatal non progressive damage to the brain often resulting in disorders of posture and movement, characterized by impaired joint stiffness. Treatment of motor impairments is based on assessment methods with a number of disadvantages. The used clinical scales are ordinal, subjective and do not allow for a further discrimination of impaired joint stiffness into its contributing components

Study objective

We propose an instrumented approach, during which the ankle is rotated in a precise and controlled way using a robot manipulator. Using neuromuscular modelling, key neuromechanical parameters as viscosity, stiffness and reflexive torque can be quantified based on reaction torque and electromyography of lower leg muscles.

We aim to apply aforementioned procedure to a group of n=40 CP patients and 10 healthy controls within a cross-sectional design to answer the following questions:
1. Do neuromechanical parameters around the ankle differ between CP patients and healthy subjects?
2. Doneuromechanical parameters, i.e. tissue stiffness, viscosity and reflex torque correlate to disorder severity as graded by the Ashworth Scale (AS) and SPAT (Spasticity Scale).

3. How are aforementioned correlations influenced by test condition, i.e. speed of joint rotation and knee angle?

Study design

Cross sectional, observational study

Study burden and risks

The risks of the measurements are minimal. The motor is safe guarded against greater displacements. The motor and other moving or fragile parts are sufficiently insulated.
The experiment takes in total about 1,5 hour including mounting and demounting in the set-up, and the clinical testing. Actual measurements will take about 30 minutes. All measurements will be passive, i.e. no effort is required for patients and subjects. The measurement time may be reduced after interim analysis (if no effect of knee angle)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Diagnosis of spastic cerebral palsy.
- Age between 6 and 18 years.
- Gross Motor Function Scale (GMFCS, see appendix) I, II or III.

Exclusion criteria

Concomitant neurological diseases.
Concomitant orthopedic problems of the lower extremities.
Casting or Botulinum toxin A injections within the previous 4 months.
Orthopedic surgery of the lower leg; orthopedic surgery in other body parts within the previous 12 months.
Tendon and tissue surgery at the lower leg.
Previous Selective Dorsal Rhizotomy or intrathecal Baclofen treatment.
Inability to take prescribed test condition (hip 70°, knee 20° and 90°).
Severe cognitive or language deficits or disturbed behavior interfering with the comprehension of instructions required to participate in the study.
GMFCS IV or V (to exclude disuse or muscle atrophy).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2010
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	NL32181.058.10