Robot-aided system identification (ROBIN) of neural and non-neural contributors to ankle joint impedance in children with CP

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON44131

Source
ToetsingOnline

Brief title
ROBIN_VU01

Condition

- Congenital and peripartum neurological conditions

Synonym
brain damage, spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Technologiestichting STW

Intervention

Keyword: Ankle impedance, Cerebral Palsy, Neuromuscular system, Nonlinear system identification

Outcome measures

Primary outcome

The primary parameters are the neuromuscular parameters:

- visco-elasticity

- optimal muscle length

- reflex torque

Secondary outcome

Secondary parameters are:

- spasticity score

- tonus score

- range of motion

- angle of catch

- joint power

- gait parameters (kinematics, kinetics and walking speed)

- selectivity of motor control (SCALE)

- the gross motor functioning measure (GMFM)

- VAS score on pain and treatment satisfaction

- Muscle belly length and lengthening

- Fascicle length and lengthening

- Pennation angle

- Tendon length and lengthening

Study description

Background summary

Interventions for spastic Cerebral Palsy (CP) patients are focused on neural and non-neural causes of raised joint impedance. However, current clinical assessment of joint impedance is based on manual, subjective tests of low resolution. In addition, these tests are limited in in discriminating these neural and non-neural components. Therefore, the clinical community is in great need of quantitative and valid assessment of neuromuscular parameters to guide therapy selection. In addition, assessments should be valid with regard to activities, such as walking. Current clinical tests are based on a passive task that is poorly related to activities in daily life.
Linear system identification and parameter estimation (SIPE) techniques are used to date to identify the neuromuscular system. However, nonlinear SIPE techniques are necessary to capture the neuromuscular system during movements such as walking, i.e. within the whole range of motion and joint torques. Therefore, it is required to test new nonlinear SIPE based idenfitication methods to objectively estimate the neuromuscular components of the ankle joint during active movement.

Study objective

Primary objective of this study is to assess the reliability and validity of the neuromuscular parameters of ankle joint impedance estimated by nonlinear SIPE technology in children with CP compared to current clinical manual tests and gait analysis. In addition, the effect of joint impedance related to interventions on the neuromuscular parameters is examined. Secondary objectives are the examination of the dose-effect in IntraThecal Baclofen (ITB) treatment and the understanding of altered joint impedance in relation to mobility in children with CP.

Study design

This study is an observational cohort study.
First, the inter- en intra-reliability of the SIPE approach will be assessed in 15 CP children and 10 TDC. Next, a baseline measurement is done for all patients and controls. The correctness of the SIPE technology will be assessed by comparing the neuromuscular parameters to clinical measures, i.e. the spasticity test with (SAIS) and without (SPAT) inertial sensors, and based on

the ability to discriminate CP from TDC children. In addition, the neuromuscular parameters will be compared to a standard performed clinical gait analysis in a subgroup of 40 CP children. The CP patients are measured again after the intervention. The effect of intervention will be based on the difference between the before and after intervention measurement. In addition, a dose-effect study is performed in the children receiving ITB-treatment. Finally, the ability of the SIPE approach to forecast therapy success will be determined and compared to the accuracy of clinical measures.

To further test the construct validity, the effect of the imposed movement profile will be examined in a small sample of the participants, by imposing more gradual velocity increases of different speeds, which better resamblences the clinically applied manual movement profiles (n=20). In addition, in a subset of the participants, it is examined whether the relation between the rotations and musle-tendon lengthening is quasi-lineair, by using standard ultrasound measurements (n=20).

Intervention

Rotations of the foot performed by the Achilles.

Study burden and risks

The protocol runs in parallel to existing clinical practice and will not affect clinical decision making. Therefore, no extra visits are required, except for the control subjects and the participants of the reliability study. The burden and risk are minimal because the measurements are non-invasive, painless and easy to perform. During a short time, active participation of patient and subjects is required. Extra measurement time does not exceed 60 minutes for robotic measurements. Safety precautions are taken comprising the restriction within the subject*s range of motion together with normal accelerations and also prevention of falling. The result will not benefit the participant, but they will contribute to the treatment of CP patients in the future. The study is focused on children with CP, since they undergo many interventions during childhood en will thus benefit from improved treatment selection.

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

- children diagnosed with spastic uni-or bilateral CP or with spastic paresis
- aged between 6 and 18 years
- with an indication for treatment of suspected high leg muscle tone, by either administration of botuline toxine or intrathecal Baclofen, serial casting or selective dorsal rhizotomy

Exclusion criteria

- additional medical problems interfering with joint neuromechanical characteristics
- range of motion (sagittal) of ankle smaller than 20 degrees
- cognitive / communicative unability to understand instructions
- insufficient mastery of the Dutch or English language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2013
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	14-02-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	25-02-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-09-2015
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-06-2016
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL41073.000.12