Validity and reliability of the Repetitive Movement Test (RMT) in children with spastic Cerebral Palsy scheduled for ITB treatment

Published: 19-11-2013
Last updated: 22-04-2024

Primary objective is to assess the reliability and assess the reliability and construct validity of the Repetitive Movement Test (RMT) as a measure of spasticity in children with CP scheduled for ITB treatment, between 6-18 year.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40286

Source
ToetsingOnline

Brief title
Validity and reliability of the Repetitive Movement Test

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: Cerebral Palsy, intrathecal Baclofen, Repetitive Movement Test, spasticity

Outcome measures

Primary outcome

Primary parameters are RMT outcomes, i.e. dynamic stretch reflex (DSR), tonic

stretch reflex (TSR) and range of motion of the ankle.

Secondary outcome

Secondary parameter is the spasticity score (SPAT).

Study description

Background summary

A common treatment for children with moderate to severe spasticity is therapy using Intrathecal Baclofen. Several clinical assessment instruments are used to measure the effect of ITB on spasticity, however, these tests are found to be subjective, ordinal and of low resolution while standardizing is lacking. Since several complications are reported for ITB treatment, an objective and valid instrument to measure the effect of spasticity and pump function is necessary. The repetitive movement test (RMT) is a relatively new measure developed and used at our department to measure spasticity, raised tonus and range of motion. While the RMT is found to be a valid and objective tool to measure the effect of ITB on spasticity in spastic adults, the validity has yet to be established in children with CP scheduled for ITB, the majority of the population seen at the department for ITB test treatment. In addition, knowledge about the reliability of the measurements would attribute to the clinical interpretation of the results and usage of the RMT to check on pump function.

Study objective

Primary objective is to assess the reliability and assess the reliability and construct validity of the Repetitive Movement Test (RMT) as a measure of spasticity in children with CP scheduled for ITB treatment, between 6-18 year.

Study design

This study is an observational cohort study. During baseline measurements, which are pre-treatment, 3 measurements will be performed by examiner 1 and one measurement by examiner 2, to assess the inter- and intra-reliability of the RMT. In addition, a post-treatment test will be performed by examiner 1 on the same test-day after administration of a test ITB doses, to assess the validity. Current clinical spasticity assessment (SPAT) will also be performed to correlate to the RMT results.

Study burden and risks

The burden is minimal, because the protocol runs in parallel to existing clinical practice and will not affect clinical decision making, so no extra visits are required. The measurements are passive and require the subject to relax. They do not last longer than 30 seconds and the whole protocol not longer than half an hour. The risks are minimal, because the measurements are non-invasive, painless and easy to perform. The measurements are already performed in clinical practice, but extra measurements are required to structural measure the validitiy and reliability.
The result will not directly benefit the participant, but they will contribute detection of pump dysfunction.
The study is focused on children with CP scheduled for ITB treatment, since they compromise the majority of the patient population starting with ITB treatment and will thus benefit from improved measurement of the effect of ITB on spasticity and detection of dysfunctioning pumps.

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

- are aged between 6 and 18 years;
- have a clinical diagnosis of spastic uni- or bilateral CP and are spastic in the ankle an/or knee;
- are indicated for treatment for suspected high muscle tone of leg muscles, by ITB.

Exclusion criteria

- Inability to bend the knee;
- there are additional medical problems interfering with joint neuromechanical characteristics;
- the child is unable to comply with the protocol, i.e. does not have the cognitive/ communicative ability to understand instructions and participate in the measurements;

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	13-02-2014
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL45254.029.13