Muscle properties in children with cerebral palsy undergoing orthopaedic surgical intervention to improve gait

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON41324

Source
ToetsingOnline

Brief title
Muscle properties in cerebral palsy after surgery to improve gait

Condition

- Neurological disorders congenital
- Soft tissue therapeutic procedures

Synonym
Cerebral palsy, spastic children

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Dr. W.M. Phelps Stichting voor Spastici

Intervention

Keyword: Cerebral palsy, Children, Muscle morphology, Orthopaedic Surgery

Outcome measures

Primary outcome

Histological, morphological and mechanical properties of the treated muscles

and tendons, and angle-moment relationship

Secondary outcome

Clinical, gait, and functional characteristics.

Study description

Background summary

Orthopaedic surgical interventions to improve gait in children with cerebral palsy (CP) have high recurrence and re-operation rate. The effects of these interventions on muscle architecture and how this relates to changes in the range of knee and ankle motion and gait are unknown.

Study objective

The aims of the proposed study are (1) to test the reliability of knee moment-angle measurements, (2) to obtain insight how muscle and tendon characteristics in children with CP contribute to the limitations in range of motion (ROM) of the knee and ankle, (3) to determine the longitudinal effects of orthopaedic surgical interventions on morphological and mechanical properties of treated muscle, and (4) to relate these to limitations of gait and functional performance.

Study design

Part 1: Reliability study; Part 2: An observational study using a longitudinal design to determine the effects of intervention; the pre-surgical situation of children with CP will be compared cross-sectionally with typically developing children.

Study burden and risks

Treatment of the children and control subjects for biopsies will not be delayed or affected in any way due to the study. Most of the measurements for children with CP are part of the standard examination in preparation of surgical orthopaedic intervention that the children will undergo. The burdens for the children and parents (longer examination time than normal) are low. The risks of the additional measurements are very low. Muscle biopsies will be taken during surgery, without any additional skin incision or prolonged anesthesia. The research will increase our knowledge regarding the mechanisms underlying the limited knee and ankle ROM in children with CP and will likely provide indications for improvement of surgical orthopaedic treatment of these children.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

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

Patients
1. Clinical diagnosis of spastic cerebral palsy
2. Indication for surgical lengthening of thigh and/or calf muscles / or injections with Botuline A-Toxine in combination with a bony procedure targeting the increase of knee extension
3. Gross Motor Function Classification System Class I-III (ability to walk with or without aids)
4. Age: 6-20 years ;Patients for reliability-study
1. Clinical diagnosis of spastic cerebral palsy
2. Gross Motor Function Classification System Class I-III (ability to walk with or without aids)
3. Age: 8-16 years
Control group (2 groups, for detailed description see protocol page 12/13):
1st:
1. Typically developing and healthy persons
2. Age: 6-20 years
2nd:
1. Planned surgical intervention during which harvesting of a control biopsy is possible without an additional skin incision or prolonged anaesthesia
2. Age: 6-40 years;Typically developing children for reliability study
1. Age: 6-40 years

Exclusion criteria

Patients
1. Treatment of muscles, which are indicated for surgical procedures, with Botuline A -Toxine within three months before surgery.
2. A pre-surgical treatment with selective dorsal rhizotomy, intrathecal baclofen pump or prior surgery of treated muscle
3. Major disease or accident one year prior to measurements or a disturbed normal activity level of the child for more than three weeks in the last half year
4. 24-hour casting for more than two weeks, that includes the treated muscle three month prior to surgery
5. Additional neuromuscular, orthopaedic, inflammatory or systemic diseases which can influence walking ability or muscle properties
6. Medication that influences neuromuscular properties three month prior to surgery
7. Parents/guardians or child do not cooperate well enough to take part in the project;Patients for reliability-study & 1st Control group:
Same as 1., 3. and 7. for patients;2nd control group:
Sames as for patient

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2015
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

ID: 27577
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36771.029.11
OMON	NL-OMON27577