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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27577

Source
Nationaal Trial Register

Health condition

Cerebral palsy, range of motion, muscle, surgery; Cerebrale parese, spieren, operatie

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Rehabilitation Medicine
Source(s) of monetary or material Support: Dr. W.M. Phelps Stichting voor Spastici

Intervention

Outcome measures

Primary outcome

Histological, morphological and mechanical properties of the treated muscles and tendons, and angle-moment relationship. These will be determined by muscle and tendon biopsies, muscle ultrasound measurements and moment-angle measurements.

Secondary outcome

Clinical, gait, and functional characteristics. Following measurements will be used: Gross Motor Function Measurement (GMFM), 6-minute walk test, Functional Mobility Scale (FMS), Mobility Questionnaire (MobQuest28), Mobility part of the Pediatric Evaluation Disability Inventory (PEDI), clinical physical examination and gait analysis.

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.

The aims of the proposed study are (1) 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, (2) to determine the longitudinal effects of orthopaedic surgical interventions on morphological and mechanical properties of treated muscle, and (3) to relate these to limitations of gait and functional performance.

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 objective

We hypothesize that the success of surgical intervention of calf and knee flexor muscles to improve gait is determined by muscle properties and the adaptation of these muscles after surgery.

Study design

Measurements will be performed before surgery (baseline), 6 weeks, 6 month, 12 month and 24 month after surgery. Muscle and tendon biopsies will be taken only once, during surgery.

Intervention

Surgical lengthening of the muscle tendon complex of thigh and calf muscles to increase the range of motion of the knee or ankle or both to improve gait.

Contacts

Public
H. Haberfehlner
VU University Medical Center
Department of Rehabilitation Medicine
Amsterdam
The Netherlands
+31 (0)20 5988507
Scientific
H. Haberfehlner
VU University Medical Center
Department of Rehabilitation Medicine
Amsterdam
The Netherlands
+31 (0)20 5988507

Eligibility criteria

Inclusion criteria

1. Clinical diagnosis of spastic cerebral palsy;

2. Indication for surgical lengthening of thigh and/or calf muscles;

3. Gross Motor Function Classification System Class I-III (ability to walk with or without aids);

4. Age: 6-20 years.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	46
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41324

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2896
NTR-old	NTR3042
CCMO	NL36771.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41324

Study results

Summary results
N/A