Trial Description

Title

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

Trial Acronym

Muscle properties after surgery in cerebral palsy (CP-MAS)

URL of the trial

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Brief Summary in Lay Language

Children with cerebral palsy (CP) develop limitations of the range of motion of the large joints (e.g. the knee). The reasons for these limitations are properly short hamstring muscles. One of the treatment option is muscle lengthening operations. Despite these operations are successful in most of the children, the limitation of range of motion reoccur in some children. The aim of this study is to investigate how muscle properties effect walking difficulties in children. Therefore we study muscle properties and relate them to range of motion of the joints and to gait. We compare children with CP to children without CP. This enables us to study the reasons of the range of motion limitation and the short and long term effects of the surgery. Additional we compare two surgical techniques: (1) the standard procedure: lengthening of all the medial hamstring muscles (2) the cutting of the tendon of only one hamstring muscle (semitendinosus).The second procedure is less burdening and shows similar results than the standard procedure.

Brief Summary in Scientific Language

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.
We perform 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. Additional two surgical procedures of lengthening of the hamstring muscles in children with CP will be compared: a simple percutaneous tenotomy of the semotendinosus muscle and a larger procedure including the semimembranosus and gracilis as well. Patients will be randomly allocated to one of the interventions.

Organizational Data

- DRKS-ID: **DRKS00004723**
- Date of Registration in DRKS: **2013/02/21**
- Date of Registration in Partner Registry or other Primary Registry: **2011/08/16**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **293/11 , Basel (Schweiz) Ethikkommission beider Basel EKBB**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1139-4224**
- Primary Registry-ID: **NTR3042 (Nederlands Trial Register)**

Health condition or Problem studied

- ICD10: **G80 - Cerebral palsy**

Interventions/Observational Groups

- Arm 1: **Lengthening of the knee flexors by tendinous lengthening of the semitendinosus muscle combined with a fractional lengthening of the semimembranosus and gracilis muscles**
- Arm 2: **Lengthening of the knee flexors by percutaneous tenotomy of the semitendinosus muscle**
- Arm 3: **Controls: typically developing children (to compare the pre-surgery situation); muscle biopsies of subject ondergoing surgery in the hamstring region (e.g. cruciate ligament reconstruction)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: **[---]***

Control: **Active control**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

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

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.
Measurements will be performed before surgery (baseline), 6-12 weeks, 6 month, 12 month and 24 month after surgery.

Countries of recruitment

- NL **Netherlands**
- CH **Switzerland**

Locations of Recruitment

- University Medical Center **UKBB, Basel**
- University Medical Center **VUmc, Amsterdam**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/02/11**
- Target Sample Size: **46**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Years**
- Maximum Age: **20 Years**

Additional 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);

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.

Addresses

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*