# Three Dimensional Ultrasound Reconstruction of the Medial Gastrocnemius in Children with Cerebral Palsy

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To optimize the 3D ultrasound reconstruction and dynamometer as a clinical tool for measurement of morphological and mechanical muscle properties, and to compare the m .gastrocnemius medialis of healthy children to the m .gastrocnemius medialis of...

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

## Summary

### ID

NL-OMON30772

**Source**
ToetsingOnline

**Brief title**
3D Ultrasound of GM in CP

### Condition

- Congenital and peripartum neurological conditions

**Synonym**
Infantile paralysis, Little's disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** Phelps-Stichting voor Spastici

## Intervention

**Keyword:** 3D ultrasound, cerebral palsy, spastic muscles

## Outcome measures

### Primary outcome

The primary study parameters will be measured in the m. gastrocnemius medialis.

These parameters will be: the muscle belly length, the muscle fibre length, the

muscle fibre angle, the muscle deep aponeuroses length, and the muscle

superficial aponeuroses length.

### Secondary outcome

None

# Study description

### Background summary

Cerebral palsy (CP) is the most common cause of motor disorder in children. 80 per cent of the reported cases of CP are predominantly spastic. In rehabilitation, most of the commonly applied therapeutic interventions are directed at lengthening of the spastic muscles. Effectiveness of intervention requires a fundamental knowledge of the mechanisms underlying the reduced muscle force and muscle length range of active force exertion as well as how the interventions change muscle force and length.
The aim of this project is to further develop and optimize a non-invasive method which allows for quantifying morphological parameter of muscles in vivo. Recent developments have made it possible to extend normal 2D B-scan ultrasound analysis of a plane to a 3D reconstruction of a volume. Based on this approach a 3D ultrasound reconstruction technique will be used to measure morphological muscle parameters such as muscle belly length, fiber length, and pennation angle. To relate these morphological muscle parameters to mechanical muscle properties such as passive muscle force and net joint moment a dynamometer will be used.

### Study objective

To optimize the 3D ultrasound reconstruction and dynamometer as a clinical tool for measurement of morphological and mechanical muscle properties, and to compare the m .gastrocnemius medialis of healthy children to the m .gastrocnemius medialis of children with SDCP using the 3D ultrasound and the dynamometer.

### Study design

- Part A: a pilot study to investigate the reproducibility of the 3D ultrasound and of
the dynamometer on healthy children.
- Part B: Investigate the reproducibility of the 3D ultrasound and the dynamometer
on children with SDCP and a descriptive study to compare healthy children to children with SDCP using the 3D ultrasound and the dynamometer.

### Study burden and risks

The reconstruction of the m gastrocnemius medialis is expected to give a better understanding of the morphology of spastic muscles. And in the (near) future, this method can improve diagnosis and treatment of spastic muscles. The additional risks of the current study for the subjects are negligible and the burdens minimal. The measurements are non-invasive. Subjects will have to lie prone on a bench, whilst undergoing the ultrasound scans and passive dynamometer measurements, watching a video. For this study it is necessary that the subjects do not move during the measurements. This will ask for some patience of the subjects. We believe the benefits clearly outweigh the risks or burdens for the subjects.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

Healthy children
- Age: between 6 and 12 years of age
- Male and female;Children with SDCP
- Clinical diagnosis of bilateral spastic cerebral palsy (GMFCS level 1-3)
- with a decreased ankle range of motion: dorsal flexion < 0º
- with the indication for treatment to improve walking ability
- Age: between 6 and 12 years of age
- Male and female

## Exclusion criteria

Healthy children
- Disorders concerning the musculoskeletal system
- Parents/guardians and/or child do not understand the Dutch language well enough to take part in this project

Children with SDCP
- Prior orthopaedic surgery of the lower limbs
- With the exception of hip adductor tenotomy
- Prior botulinum toxin A injection: < 16 weeks
- Additional disorders (other than CP) concerning the musculoskeletal system
- Parents/guardians and/or child do not understand the Dutch language well enough to take part in this project

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2008 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 20-05-2008 |
| Application type: | First submission |
| 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 | NL15010.029.07 |