Quantitative muscle ultrasound of orofacial muscles in children with cerebral palsy

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- What is the echogenicity (quantitative described as z-scores, based on own laboratory values and qualitatively described as Heckmatt gradations) of orofacial muscles (digastrics muscle, geniohyoid muscle, masseter muscle, temporal muscle) in…

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

Summary

ID

NL-OMON46117

Source
ToetsingOnline

Brief title
Orofacial muscle ultrasound in CP

Condition

- Congenital and peripartum neurological conditions

Synonym
spasticity

Research involving
Human

Sponsors and support

Primary sponsor: afdeling Logopedie (kinderen), Afdeling Revalidatie
Source(s) of monetary or material Support: Ministerie van OC&W,Phelps stichting

Intervention

Keyword: Cerebral palsy, orofacial muscles, Ultrasound

Outcome measures

Primary outcome

- Thickness of orofacial muscles (digastrics muscle, masseter muscle, temporal muscle, tongue) and described as z-score (corrected for age, height and weight, based on own laboratory normal values).

- Echogenicity of orofacial muscle (digastrics muscle, geniohyoid muscle, masseter muscle, temporal muscle) and described as z-score (corrected for age, height and weight, based on own laboratory normal values).

Secondary outcome

- Performance of mastication (Mastication Observation Evaluation)

- EDACS level

- Drooling Quotient

- Timed Test of Swallowing (ml/sec)

- Pediatric Posterior Drooling Scale

Study description

Background summary

Children with cerebral palsy (CP) often have dysphagia (prevalence of 43 - 99%) depending on the severity of the motor impairment. Observation of eating and drinking and instrumental assessment (videofluoroscopic swallowing study) are used to give a description of the eating and swallowing skills. However, these assessments do not give insights in the underlying pathophysiology of the problems: which muscles are affected in which way?
In the last years, quantitative muscle ultrasound is used in children with neuromuscular disorders. With muscle ultrasound, the thickness and echogenicity

of a muscle can be determined. The echogenicity reflects the degree of density of the measured tissue. Muscle tissue has a low echogenicity, and fat or connective tissue and bone have a high echogenicity. Quantitative muscle ultrasound of orofacial muscles provides insight into the underlying pathological mechanisms of mastication and swallowing difficulties.
With the current research, a precise picture can be obtained of the (changed) composition of the orofacial muscles and the relation with eating and swallowing problems in children with CP. This knowledge can be a next step in understanding the complex swallowing problems of the group of children with CP and the way in which therapy has to be started in the form of exercises and compensations. The different orofacial muscles (submental muscles, masticatory muscles) all have their own function and influence on the activity to be performed. If we have more insight in the affected muscles, we could also examine whether influencing is possible through exercise. By visualizing these muscles we can better explain the underlying mechanisms involved. With this knowledge more differentiation can be made in therapy. This means an important step for patients (and their parents) towards a better substantiated and more targeted treatment of eating and swallowing problems in children with CP.

Study objective

- What is the echogenicity (quantitative described as z-scores, based on own laboratory values and qualitatively described as Heckmatt gradations) of orofacial muscles (digastrics muscle, geniohyoid muscle, masseter muscle, temporal muscle) in children with CP?
- What is the thickness (quantitative described as z-scores, based on own laboratory normal values) of orofacial muscles (digastrics muscle, masseter muscle, temporal muscle and the tongue) in children with CP?
- Is there a relation between the echogenicity of orofacial muscles in children with CP and the EDACS-level or other functional outcome measurements (about mastication, swallowing and saliva control) and/or patient characteristics (GMFCS, age, BMI)?
- Is there a relation between the thickness of orofacial muscles in children with CP and the EDACS-level or other functional outcome measurements (about mastication, swallowing and saliva control) and/or patient characteristics (GMFCS, age, BMI)?

Study design

In 50 children with CP, visiting the outpatient clinic for Speech Language Therapy, orofacial muscle ultrasound will be performed. Thickness and echogenicity of orofacial muscle will be determined and will be described as z-scores, corrected for age, height and weight (based on own laboratory values). Children will be classified using the Eating and Drinking Ability Classification System (EDACS). In all EDACS- levels (I-V), 10 patients with CP will be included. Functional outcome measurements on mastication, swallowing

and saliva control (regular measurements during assessment in the Amalia Children*s Hospital of the Radboudumc) will be described.

Study burden and risks

Time investment: 10 minutes within a regular visit at the outpatient clinic for Speech and Language therapy.
There are no risks associated with participation to the study. The ultrasound assessment is not invasive. For other patientgroups (neuromuscular diseases) the ultrasound assessment is within regular care.

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

Age 3-18 years
Diagnosis of spastic cerebral palsy
Signed informed consent by parents (and the patient when aged above 12 years).

Exclusion criteria

- Medication to reduce saliva production (glycopyrrolate, scopolamine, trihexyfenidyl)
- Treatment with botulin toxin injections in the salivary glands in the past 32 weeks
- Surgical treatment for drooling in the past.
These exclusion criteria are included because they influence the functional outcome measurements.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-11-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	24-09-2018
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66563.091.18