Dysphagia in Neuromuscular diseases, pathophysiology and treatment implications

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The objective is to describe the nature and underlying (neuromuscular en biomechanical) factors of dysphagia in different neuromuscular diseases in relation to different consistencies of food. Identifying the contributing factors are starting points...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON34892

Source
ToetsingOnline

Brief title
Dysphagia in neuromuscular diseases

Condition

- Neurological disorders congenital
- Appetite and general nutritional disorders
- Neuromuscular disorders

Synonym
Muscle diseases, Neuromuscular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Deelonderzoek voor groep 1 wordt gefinancierd door het Duchenne Parent project

Intervention

Keyword: Adults, Children, Dysphagia, Neuromuscular diseases (NMD)

Outcome measures

Primary outcome

Group 1 and 2:

- Complaints and symptoms of swallowing problems

- Degree of (dys)function of the mandible with objective (mandibular opening in mm, description of craniofacial and dental occlusions) and subjective measures (MFIQ)

- sEMG of the submental muscle group during swallowing of thin liquid, semi solid and solid food with different head postures (duration (in sec) and amplitude (in µV))

- Dysphagia limit (in sec)

- Maximal tongue pressure (in mmHg) during swallowing of thin liquid, semi solid and solid food

- Information of the oral, pharyngeal and esophageal phase of swallowing from the videofluoroscopic swallow study

- Echo density of the tongue structure and muscle thickness representing the ratio muscle - connective tissue

Group 3:

- Degree of (dys)function of the mandible with objective (mandibular opening in

mm, description of craniofacial and dental occlusions) and subjective measures

(MFIQ)

- sEMG of the submental muscle group during swallowing of thin liquid, semi

solid and solid food with different head postures (duration (in sec) and

amplitude (in µV))

- Dysphagia limit (in sec)

- Maximal tongue pressure (in mmHg) during swallowing of thin liquid, semi

solid and solid food

- Echodensity of the tongue structure and muscle thickness representing the

ratio muscle - fibrous tissue

Secondary outcome

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Study description

Background summary

Swallowing problems are not uncommon in different neuromuscular disorders (NMD) including Duchenne Muscular Dystrophy (DMD). Common mechanism seem to be present leading to dysphagia. The dysphagia can be partly explained from neurological factors (paresis, coordination), but also biomechanical factors appear to play a role (recent research in children with SMA type II). In different types of NMD these problems are mostly described in chewing, but also pharyngeal residues after the swallow are observed. In NMD little is known about the contribution of the tongue, submental muscle group and movement of the hyoid in the swallowing process. This last factor is influenced as well by the position of the head on the neck and is therefore dependent on pareses of the neck muscles. Also very little is known about the influence of the consistency of the food. In children with SMA type II it is shown that apart from neurological also biomechanical factors, like head position, play a role in combination with the consistency of food.

Study objective

The objective is to describe the nature and underlying (neuromuscular en biomechanical) factors of dysphagia in different neuromuscular diseases in relation to different consistencies of food. Identifying the contributing factors are starting points for therapeutic interventions.

Study design

The design is a descriptive design (case series) with different groups of children and adults involved, with dysphagia caused by neuromuscular diseases. Variables are gathered with an extensive swallowing assessment. To gather normal values some of the items of the swallowing assessment will be done in a healthy control group with comparable ages.
The study consists of 3 sub studies:
- A study of the swallowing mechanisms in boys and young adults with DMD. The increasing paresis is known which is leading to problems in chewing in this population. The influence of progression of the disease on dysphagia will be assessed, aimed to the neurological and biomechanical factors in relation to different consistencies of food.
- A study of different types of NMD with known neurological head and mouth problems but differing from each other. To what extend the neurological and biomechanical factors play a role in the pathophysiology of dysphagia will be assessed, as well the relation with different consistencies of food.
- Collecting normal values in healthy people. On this moment there are no normal values for the innovative research methods that will be used in this study

Study burden and risks

There will be minimal risk, because the measurements are not invasive, not long standing and will be done only once. The risks for the group (children) are negligible and the burden is minimal. The research will be done in presence of the parents, who were informed. Also for the children is information available.

Contacts

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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

Inclusion (group 1 and 2):
- Diagnosis DMD (group 1), NMA (group 2)
- Chewing and / or swallowing problems (problems with deglutition, choking, coughing, or the feeling of food sticking in the throat);Inclusion (group 3):
- Between 5 and 65 years, without health problems which can lead to dysphagia

Exclusion criteria

Exclusion (group 1 and 2)
- Totally fed by tube (non oral feeding)
- Other pathology than NMD causing chewing or swallowing problems
Exclusion (group 3):
- Pathology with chewing or swallowing problems

Study design

Design

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

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2010
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	NL30723.091.09