Coordination of trunk, head and arm movements during functional tasks, in healthy children and children with Duchenne muscular dystrophy, spinal muscular atrophy and cerebral palsy.

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First objective: gain insight in the coordination of trunk, head and arm during functional tasks in healthy children and compare this with the coordination in children with DMD, SMA and CP. Second objective: investigate if newly developed supportive...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45000

Source
ToetsingOnline

Brief title
Upper body movement during functional tasks

Condition

- Muscle 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: STW,BAAT medical,BAAT medical;Focal;FSHD Foundation;FED;PPMD;DPP;Intespring;Hankamp;Summit revalidatietechniek,Focal,Hankamp,Intespring,Summit revalidatietechniek

Intervention

Keyword: Coordination, Movement, Neuromuscular diseases, Upper body

Outcome measures

Primary outcome

The primary study parameters will be the active range of trunk and head motion (e.g. motion in one direction), dynamic range of trunk and head motion (e.g. during functional arm tasks), maximal sEMG amplitude during movements as percentage of EMG amplitude in maximal voluntary contraction (MVC) and a trunk impairment classification score.

Secondary outcome

Secondary study parameters will be the force and/or pressure profiles as parameters for balance and stability of the trunk, and for determination of the kinetics.

Study description

Background summary

Children with neuromuscular diseases suffer from muscle weakness, which results in activity limitations. The coordination between arm, trunk and head movements is very important in performing activities of daily life (ADL) from a wheelchair. Weakening of the muscles causes limitations in performing activities independently, resulting in a decrease in autonomy and quality of life.
While the coordination of arm, trunk and head movements is key in performing

functional tasks, the focus in literature and in the development of supportive devices, is mainly on one of the three body parts. Current arm supportive devices improve the activity level of the patients, but they cannot function optimally because of the lack of trunk and head support.
A trunk and head supportive device will be developed, which also can interact with the arm supportive device, in collaboration with several technical universities. Therefore more insight is needed in the coordination between trunk, head and arm movements in healthy children and children who suffer from muscular weakness (i.e. Duchenne Muscular Dystrophy (DMD), Spinal Muscular Atrophy (SMA) and Cerebral Palsy (CP)).

Study objective

First objective: gain insight in the coordination of trunk, head and arm during functional tasks in healthy children and compare this with the coordination in children with DMD, SMA and CP. Second objective: investigate if newly developed supportive devices/prototypes are able to support the trunk and head effectively during arm movements.

Study design

Explorative, cross-sectional study

Study burden and risks

The burden and risk associated with participation is limited, since the measurements are non-invasive and the intensity is relatively low. The measured movements are movements also performed during activities of daily living and will not be forced.

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

- Between age of 6 and 20 years
- Able to show arm motor skills at request
- For patient groups: genetically confirmed diagnosis of Duchenne muscular dystrophy or clinically confirmed diagnosis of cerebral palsy

Exclusion criteria

- Other disabling diseases affecting the trunk, head or arms
- Surgical scoliosis correction
- Participating in other studies at the same time

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2015
Enrollment:	71
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-12-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2018
Application type:	Amendment
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	NL53143.091.15