The arm functions and abilities of boys with Duchenne muscular dystrophy explored by movement analysis

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Primary Objectives:1: Gain insight in the way arm function changes during the natural course of DMD through 3D movement analysis, surface electromyography and ambulant activity monitoring.2: Investigate if a newly developed exoskeleton is able to...

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

Summary

ID

NL-OMON37466

Source
ToetsingOnline

Brief title
Duchenne dynamic arm study (DDAS)

Condition

- Muscle disorders

Synonym
Duchenne muscular Dystrophy (DMD), muscular dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Ambroise,Focal Meditech,OIM Orthopedie,UPPMD;PPMD;OIM;Focal;Ambroise;Spieren voor Spieren;Princes

Biatrixfonds;Focal Meditech B.V.;Johanna Kinderfonds;Kinderrevalidatiefonds;Adriaanstichting en Biofarmind award Elizabeth

Intervention

Keyword: Arm function, Disease progression, Duchenne muscular dystrophy

Outcome measures

Primary outcome

The main study parameters are: maximal sEMG amplitude during movements as percentage of EMG amplitude in Maximum Voluntary Contraction, active range of motion and activity level during a longer period of time.

Secondary outcome

Secondary study parameters are: a questionnaire on medical history, drug use and activity level, passive range of motion, absolute muscle force, fatigue, pain and quantitative ultrasound for measuring muscle volume and muscle quality

Study description

Background summary

Due to progression of the disease a boy with Duchenne Muscular Dystrophy (DMD) will lose gradually his arm function after he gets wheelchair confined. A possible solution to compensate the loss of arm function is the development of an exoskeleton. To give input to the technical engineers of such an exoskeleton, more insight in the patterns of deterioration is needed.
A pilot study, using 3D movement analysis combined with surface electromyography (sEMG) has proven to be a new effective way of studying the course of disease. Therefore this method is used to determine the course of deterioration in a larger group of boys with DMD.

Study objective

Primary Objectives:

1: Gain insight in the way arm function changes during the natural course of DMD through 3D movement analysis, surface electromyography and ambulant activity monitoring.
2: Investigate if a newly developed exoskeleton is able to support the arm functions and activities in boys with DMD effectively.
3: To examine the possibility of activity classification of arm movements of people with DMD with the use of ambulatory motion monitoring.

Study design

Explorative case control study

Study burden and risks

The burden and risks associated with participation are very small. The movements that are measured are movements that are also performed in daily living and the movements will not be forced. Furthermore, the measurement protocol is not invasive.

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

DNA established diagnosis of DMD
Brooke scale 1-5

Exclusion criteria

Other disabling diseases influencing upper extremity function
Boys <= six years old
Surgical scoliosis correction

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2013
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	27-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-07-2014
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	NL39126.091.12