Arm training in boys with Duchenne Muscular Dystrophy

Published: 01-11-2012
Last updated: 15-05-2024

To determine whether 3D arm training with arm-support is effective in delaying the loss of arm functions in daily activities from an early age onwards in boys with DMD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON37157

Source
ToetsingOnline

Brief title
Arm training in DMD

Condition

- Musculoskeletal and connective tissue disorders congenital
- Muscle disorders

Synonym
Duchenne

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Duchenne Parent Project

Intervention

Keyword: Arm, Duchenne Muscular Dytrophy, Exercise training, RCT

Outcome measures

Primary outcome

The primary outcome will be the Motor Function Measure (MFM).

Secondary outcome

Secondary outcomes will be: the Abilhand, joint range of motion (ROM), muscle echo intensity (EI), lab-based structured 3D movement analysis combined with surface electromyography (sEMG), accelerometry, a quality of life questionnaire and the Performance of the upper limb for DMD (PUL).

Study description

Background summary

Boys with Duchenne Muscular Dystrophy (DMD) lose their independency for several activities of daily life (ADL) soon after the onset of wheelchair-dependency due to muscle weakness of the upper extremity. Nowadays, there are promising modern arm-supports becoming available that re-enable patients with proximal arm weakness to functional use their arms by providing external mechanical compensation for muscle weakness of upper arm and shoulder. However, to make optimal use of these modern arm-supports patients should maintain joint mobility and muscle elasticity. Results from previous pilot studies indicate that assisted functional arm-training can delay the secondary functional deterioration caused by disuse. A three-dimensional (3D) training of both arms, starting at an early age, to maintain arm function could even be more useful but this has not been investigated yet.

Study objective

To determine whether 3D arm training with arm-support is effective in delaying the loss of arm functions in daily activities from an early age onwards in boys with DMD.

Study design

Explorative Randomized Controlled Trial (RCT)

Intervention

Boys in the intervention group will receive an assisted 3D arm training for 24 weeks. They will train both arms during 15-min sessions for 5 days per week at home. Training will consist of a virtual reality game that stimulates the boys to use their arms in three directions while using an arm-support. The control group will receive the same intervention after their waiting list period.

Study burden and risks

Burden associated with participation will be limited, since measurements are non-invasive and the risk of overexertion is limited as the training-intensity will be relatively low. Signs of overexertion (excessive muscle pain during the training, prolonged post-exercise muscle pain, a severely uncomfortable feeling during or after the training, and (extreme) fatigue) will also be investigated by a postal questionnaire once every two weeks, and in the case of overexertion training will be adjusted. In addition, from previous studies it is expected that the interventions are beneficial and may help to preserve functional abilities for a longer period.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525 GC
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 4
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* A DNA-established diagnosis of DMD
* Boys who are ambulant of wheelchair-dependent and:
- can raise arms (at least one arm) above head only by flexing the elbow (shorthning the circumference of the movement) or using accessory muscles during 10 repetitions, or
- cannot raise hands above head, but can raise an 8-oz glass of water to the mouth, or
- can raise both hands to the mouth, but cannot raise an 8-oz glass of water to the mouth

Exclusion criteria

* Boys <7 years old
* Boys who are still able to raise both arms 10 times above head without flexing the elbow or without using accessory muscles
* Other disabling diseases influencing mobility
* Boys with a clinical symptomatic cardiomyopathy
* Boys who cannot bring their hands to the mouth
* Boys who participate in another intervention trial that aims to delay physical deterioration. In particular patients that already participate in an Antisense oligonucleotide (AON)-induced exon skipping study, which may alter the course of the disease.

Study design

Design

Study phase:	2
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-08-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-01-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-10-2014
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

ID: 27200
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41708.091.12
OMON	NL-OMON27200