Rust Roest: wat kunnen we winnen aan functionaliteit met training bij jongens met Duchenne spierdystrofie?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23036

Source
NTR

Brief title
NUD study (public acronym in Dutch: Rust Roest)

Health condition

Duchenne Muscular Dystrohy (DMD), dynamic training, functional training,

In Dutch: Duchenne spierdystrofie, dynamische training, functionele training

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre, department of Rehabilitation and department of Clinical Neurophysiology
Source(s) of monetary or material Support: Duchenne Parent Project

Intervention

Outcome measures

Primary outcome

Primary outcomes for study 1 will be muscle endurance and functional abilities, as assessed with with bicycle ergometry and the Motor Function Measure (MFM). The primary outcome for study 2 will be functional abilities of the upper extremity (reaching and lifting), as assessed with the Action Research Arm test (ARA).

Secondary outcome

Secondary outcomes for both studies will be at the level of body functions and structures (e.g. muscle tissue), activities (e.g. activities in daily life) and participation (e.g. health related quality of life).

Study description

Background summary

Rationale:

"Use it or lose it" is a well known saying and is to some extent also applicable to boys with Duchenne Muscular Dystrophy (DMD). Boys with DMD have reduced muscle mass, muscle strength, muscle endurance and, therefore, loss of functionality. The increasing effort to perform certain activities, fear of falling and the need of personal aids (like an electric wheelchair) may limit leg and arm functions as a result of disuse. An important aim in the management of DMD is to preserve functional abilities as long as possible, since there is still no curative (pharmaco)therapy. It is hypothesized that, in the case of disuse, training may help to gain functional abilities or preserve them.

Objective:

The primary objective of this project is to contribute to the knowledge of the optimal medical care of DMD patients with regard to the optimal level of physical activity by examining the effects of training primarily upon muscle endurance and/or the functional abilities of boys in different stages in the course of DMD.

Study population:
The NUD study will consist of two studies: study 1 ¡¯Dynamic leg and arm exercise training for ambulant or recently wheelchair confined boys with DMD¡¯ and study 2 ¡®Functional training with arm support for boys with DMD who have been wheelchair confined for several years¡¯. Thirty and ten boys with a DNA established diagnosis of DMD will be included in each study, respectively. The two different groups that will be included are:

1. Boys who are at the end of their ambulation phase or who are recently wheelchair confined;

2. Boys who have been wheelchair confined already for several years.

Study design:
Study 1 will be an explorative (randomized controlled) trial with multiple baseline measurements. Boys will be randomly assigned to either the intervention group or the control group (waiting list). Repeated measurements will be done during the first two months, followed by a six months training intervention period. The control group will get the same intervention after the waiting period. Study 2 will be a repeated measurements design, starting with a two months period for baseline measurements, followed by a six months period in which a training intervention is given.

Intervention:
The intervention of study 1 will consist of a low-to-moderate intensity dynamic exercise training. Boys will train their legs and arms with active-passive cycling equipment. The intervention of study 2 will be a functional training of the non-dominant arm and hand with arm support.

Main study parameters/endpoints:
Primary outcomes for study 1 will be muscle endurance and functional abilities of the lower and upper extremities, as assessed with bicycle ergometry and the Motor Function Measure (MFM). The primary outcome for study 2 will be functional abilities of the upper extremity (reaching, lifting, manipulating), as assessed with the Action Research Arm Test (ARAT). Secondary outcomes for both studies will be at the level of body functions and structures (e.g. muscle tissue), activities (e.g. activities in daily life) and participation (e.g. health related quality of life).

Study objective

It is expected that dynamic leg and arm training and functional training with arm support can retard the progression of the disease at the level of muscle endurance and/or the functional abilities of the lower and/or upper extremity in boys who are in different stages in the course of Duchenne Muscular Dystrophy (DMD).

Study design

Study 1 will be an explorative (randomized controlled) trial with multiple baseline measurements. Boys will be randomly assigned to either the intervention group or the control group (waiting list). The total study time will be sixteen months. Repeated measurements will be conducted during the baseline period, training intervention period and follow-up. Six and nine measurements will be performed in the intervention group and the control group, respectively.

Study 2 will be an (uncontrolled) repeated measures design. After a two months period for baseline measurements, intervention training is given for six months with measurements

after three and six months. Finally, one extra measurement will be done after three more months to evaluate to what extent the possible effect of training has lasted.

Intervention

The intervention of study 1 will consist of a low-to-moderate intensity dynamic exercise training. The control group will get the same training intervention after the waiting period. The intervention of study 2 will be a training of the non-dominant arm with arm support.

Contacts

Public
UMC St Radboud
Reinier Postlaan 4
Merel Jansen
Nijmegen 6525 GC
The Netherlands
+31 (0)24 3668195
Scientific
UMC St Radboud
Reinier Postlaan 4
Merel Jansen
Nijmegen 6525 GC
The Netherlands
+31 (0)24 3668195

Eligibility criteria

Inclusion criteria

Study 1 'Dynamic leg and arm exercise training for ambulant or recently wheelchair confined boys with DMD':

1. DNA established diagnosis of DMD;

2. Boys who are at the end of their ambulation, and;

3. Need more than 5 seconds to get up from the floor or are not able to raise from the floor, and/or;

4. Are not able to bicycle without assistance, and/or;

5. Are wheelchair dependent to move over long distance (more than 500m);

6. Boys who are recently wheelchair confined (approximately 1-2 years after they've stopped walking) and;

7. Are able to stand (un)supported;

8. Are able to touch the top of their head with both hands without assistance.

Study 2 'Functional training with arm support for boys with DMD who have been wheelchair confined for several years':

1. DNA established diagnosis of DMD;

2. Boys who have been wheelchair confined for a few years (approximately 2-5 years after stop walking);

3. Boys who have problems with lifting their arms and reaching, and;

4. Are unable to touch the top of their head (at least one hand);

5. Are able to use their hands for daily activities;

6. Experience difficulties in lifting their arms and reaching.

Exclusion criteria

Study 1:

1. Other disabling diseases influencing mobility;

2. Boys with a clinical symptomatic cardiomyopathy;

3. Boys <6 years old.

Study 2:

1. Other disabling diseases influencing mobility;

2. Boys who are able to stand;

3. Boys >20 years old;

4. Boys who already use an arm support.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2009
Application type:	First submission

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
NTR-new	NL1553
NTR-old	NTR1631
Other	CMO/ABR : 2008/185/NL21842.091.08.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A