Energy cost of walking in boys with Duchenne muscular dystrophy; a reproducibility and sensitivity study

Published: 03-03-2010
Last updated: 04-05-2024

1. To determine the reproducibility and sensitivity of the EC of walking test in boys with DMD, in comparison with the reproducibility and sensitivity of the 6MWT. 2. To evaluate the one-year course of limitations in ambulation among boys with DMD,...

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

Summary

ID

NL-OMON38268

Source
ToetsingOnline

Brief title
Energy cost of walking in boys with Duchenne

Condition

- Neuromuscular disorders

Synonym
Duchenne muscular dystrophy; DMD; progressive muscular disease in boys

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Prosensa Therapeutics B.V.

Intervention

Keyword: Duchenne, Energy cost of walking, Functional course, Reproducibility

Outcome measures

Primary outcome

Primary study parameters

-Speed (m/min)

-Net energy cost (J/kg/m)

-6-minute walking distance (m)

Secondary outcome

Secondary study parameters

-Participation in daily activities and social roles

-Intensity of participation

-Perceived exertion

Additional study parameters

-Age (yrs)

-Height (cm)

-Body-mass (kg)

-Leg length (cm)

Study description

Background summary

Many boys with Duchenne muscular dystrophy (DMD) describe limitations in ambulation. The course of these limitations can be measured with the 6-minute

walking test (6MWT) or with the energy cost (EC) of walking test. However, information on the reproducibility and sensitivity of both these tests in boys with DMD is unknown, and has never been described in the literature. This lack of knowledge is a major drawback for choosing the most appropriate functional measurement tool in clinical trials among boys with DMD.

Study objective

1. To determine the reproducibility and sensitivity of the EC of walking test in boys with DMD, in comparison with the reproducibility and sensitivity of the 6MWT.

2. To evaluate the one-year course of limitations in ambulation among boys with DMD, as quantified with the EC of walking test and 6MWT.

Study design

In order to determine the reproducibility of the EC of walking test and the 6MWT in boys with DMD, an intra-rater test-retest reproducibility study will be conducted at the outpatient clinic of the department of Rehabilitation medicine in the VU University medical center (VUmc) in Amsterdam.

Study burden and risks

Benefits: this study will show whether the EC of walking test is a more reproducible and sensitive test than the 6MWT. This information is important for choosing the most appropriate functional measurement tool that can be used in studies evaluating the effect of therapies and treatment in boys with DMD.
Risks and burden: the risk for the patients in this study is negligible. Also, the burden for the patients is low; per visit two sub-maximal walking tests will be performed (comparable to walking in daily-life), with bouts of (seated) rest in between the different parts of the experiment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-children diagnosed with Duchenne muscular dystrophy
-children aged between 6 and 14 years
-children capable of walking independently for more than 150m without any supportive devices.

Exclusion criteria

-children who underwent surgery (<6 months ago)
-children who are unable to follow simple instructions;
-children who have behavioural problems that compromise participation in the study

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):	23-04-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL29858.029.09