Evaluation of hand function in patients with Duchenne muscular dystrophy, including an additional pilot study with a newly designed glove. An explorative study.

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To examine the natural disease course in the hands of persons with DMD and to explore relations between the level of body function/structures and the level of activities, according to the ICF model.

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

Summary

ID

NL-OMON41821

Source
ToetsingOnline

Brief title
Hand function in Duchenne.

Condition

- Neuromuscular disorders

Synonym
Duchenne disease, Duchenne muscular dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiegeneeskunde
Source(s) of monetary or material Support: vanuit opleidingsgelden voor medisch specialist (revalidatiegeneeskunde)

Intervention

Keyword: Activities, Disease course, Duchenne muscular dystrophy, Hand function

Outcome measures

Primary outcome

The primary goal of this study is to examine the natural disease course in the hands of persons with DMD. We will evaluate two different levels of human functioning according to the International Classification of Functioning, Disability and Health (ICF) model; the dimension of body function and structures as well as the dimension of activities.

To measure strength and function we will use the recently developed tools MyoPinch, MyoGrip and MOVIPLATE. To assess the presence of contractures we will measure range of motion using goniometry. To evaluate and describe activities we will use several instruments, including Brooke, MACS, PUL, Timed-TIHM and CUE. We will perform an additional pilot in 5 to 15 patients where we will measure hand kinematics with a recently designed glove (TU Twente).

Secondary outcome

Secondary goals of this study are to explore relations between these two levels, the possible difference between the dominant and non-dominant hand, and possible influence of posture and/or training or splints.

Study description

Background summary

The distal muscles of the arm are the best-preserved muscle groups until the later disease stages in boys/men with Duchenne muscular dystrophy (DMD), as described in published literature. With the increased life expectancy it is of great importance to maintain as many abilities as possible to perform activities of daily living; to manipulate assistive devices and use a mobile phone for example. Not much is known about the natural disease course in the hands of persons with DMD and in particular the possible relations between the different levels of functioning according to the ICF model. In our explorative study we will search for potential relations between the level of body structures/functions and the level of activities. The results might influence and/or increase therapeutic options in the future.

Study objective

To examine the natural disease course in the hands of persons with DMD and to explore relations between the level of body function/structures and the level of activities, according to the ICF model.

Study design

An explorative study with a cross-sectional design.

Study burden and risks

Burden associated with participation will be limited, since measurements are non-invasive. Patients may experience some fatigue and/or muscle pain. Since there is no training in our study we believe this possibility is very small.

Contacts

Public
Selecteer

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Scientific
Selecteer

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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

A DNA-established diagnosis of DMD
Informed consent

Exclusion criteria

Presence of other disabling disease(s) with (major) influence on strength, mobility or activities, especially concerning the hand.
Unable to cooperate with or understand testing

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):	26-10-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2015
Application type:	First submission
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	NL52246.091.15