Applicability of an arm exoskeleton for persons with Duchenne Muscular Dystrophy and Spinal Muscular Atrophy

Published: 02-01-2017
Last updated: 15-04-2024

The primary objective of this study is to evaluate upper extremity and trunk function in persons with SMA in different stages of the disease using 3D movement analysis, muscle force measurements, surface electromyography and activity scales. The...

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

Summary

ID

NL-OMON45622

Source
ToetsingOnline

Brief title
Arm exoskeleton for DMD and SMA

Condition

- Neurological disorders congenital
- Neuromuscular disorders

Synonym
DMD / Spinal Musclular Atrophy, Duchenne Muscular Dystrophy, SMA

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO Toegepaste Technische

Wetenschappen,Prinses Beatrix Spierfonds

Intervention

Keyword: Duchenne Muscular Dystrophy, Exoskeleton, Spinal Muscular Atrophy, Upper extremity

Outcome measures

Primary outcome

The most important outcome measures are: maximal muscle force, active range of motion, muscle activity measured with surface electromyography and trunk impairment score.

Secondary outcome

Secundary outcome measures are: passieve range of motion, trunk balance and stability, performance of upper limb scale, 9-hole peg test, Timed_TIHM en Brooke scale.

Study description

Background summary

Duchenne Muscular Dystrophy (DMD) and Spinal Muscular Atrophy (SMA) are progressive neuromuscular disorders which affects arm, trunk and hand function. Weakened arm and trunk function has a huge impact on independence and quality of life, especially when wheelchair confined. As a result new tools are needed that can support arm and trunk function. An arm exoskeleton might be an effective method to support the arms of people with DMD and SMA, and thereby improve daily functioning. However for further development of such an exoskeleton (which has been developed for people with DMD in a previous study), more knowledge is needed on the arm, trunk and hand function of people with SMA (this knowledge has already been obtained in DMD patients). In addition, an improved version of the exoskeleton needs to be evaluated in both DMD and SMA patients.

Study objective

The primary objective of this study is to evaluate upper extremity and trunk function in persons with SMA in different stages of the disease using 3D movement analysis, muscle force measurements, surface electromyography and activity scales. The secondary objective is further development and evaluation of the passive A-Gear in people with DMD and SMA, using both home-based and lab-based measurements.

Study design

Explorative cross-sectional study

Study burden and risks

The burden and risks associated with participation are 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

Public
Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier postlaan 4
Nijmegen 6500 HB
NL

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 or SMA
Brooke scale 1 to 4
Ambuland and non-ambulant

Exclusion criteria

Participants younger than 7 years
Other disabling diseases influencing upper extremity function

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2017
Enrollment:	26

Type:	Actual

Medical products/devices used

Generic name:	passive A(bility)-Gear
Registration:	No

Ethics review

Approved WMO Date:	02-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2017
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	NL58988.091.16