Dynamic consequences of arm support on shoulder loads, stability and associated muscular effort in people with FSHD

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(I) Compare shoulder loads estimated with musculoskeletal simulations, stability and associated muscular effort of subjects with FSHD and healthy controls during the performance of standardized upper extremity tasks with and without an arm support...

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

Summary

ID

NL-OMON46136

Source
ToetsingOnline

Brief title
Dynamic consequences of arm support on shoulder function

Condition

- Neurological disorders congenital
- Muscle disorders

Synonym
muscular dystrophy, neuromuscular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: STW,Focal Meditech BV

Intervention

Keyword: arm support, neuromuscular disease, shoulder function

Outcome measures

Primary outcome

The primary outcome measures are shoulder loads and muscular effort

Secondary outcome

The secundary outcome measure is shoulder load calculated from intertial

magnetic measurements

Study description

Background summary

For people with Facioscapulohumeral dystrophy (FSHD), an assistive device in the form of an arm support can effectively increase the range of motion by compensating for the arm weight, thus ultimately resulting in an increased functionality. However, the exact implications of arm support systems on shoulder load, shoulder instability and muscle weakness have not been properly investigated so far. Furthermore, current use rates of arm support systems are sub-optimal. Users of these arm-support systems state that the device does not fit their needs. To achieve a better fit however, a more thorough understanding of the interaction between the user and the assistive device during activities of daily living is necessary. Subjects will be asked to execute a standardized movement protocol in the lab with and without using an arm support system. In preparation of transferring to home measurements, movements will be recorded with a portable measurement system in addition to traditional, laboratory bound, motion capture equipment and EMG.

Study objective

(I) Compare shoulder loads estimated with musculoskeletal simulations, stability and associated muscular effort of subjects with FSHD and healthy

controls during the performance of standardized upper extremity tasks with and without an arm support. (II) Establish the feasibility and validity of musculoskeletal shoulder load predictions in ambulatory settings.

Study design

Cross-sectional study in which two groups will be compared; a healthy group of adults acting as control group and a group of adults with FSHD. Both groups will be asked to complete the same movement protocol with and without arm support.

Study burden and risks

The experiment consists of a single non-invasive measurement session, is non-therapeutic in nature, and requires about two and a half hour. Given that the movement-tasks lie within the range of activities of daily living, risk of injury and burden for the participants are considered to be minimal. Currently, limited information about the kinematic and dynamic changes in shoulder functioning when using an arm-support is available for people with FSHD. Obtaining this information cannot be done without investigating people with FSHD, while they are using an arm-support system. Only limited reference values concerning these kinematic and dynamic changes in shoulder functioning while using an arm-support system exist. Therefore it is important to obtain insight in these changes in healthy adults as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy: aged between 18-75 years old, able to read/understand Dutch, able to give informed consent
People with FSHD: aged between 18-75 years old, able to read/understand Dutch, able to give informed consent, able to transfer from wheelchair to chair with side- and lower back-rest, Brooke scale 3 or 4 (3 of both)

Exclusion criteria

Healthy: impaired arm/shoulder function, presence of pain in the shoulder, history of severe trauma of the shoulder in the previous two years (e.g. fracture, luxation)
People with FSHD: comorbidities that impair arm/shoulder function, incapable of abducting or elevating the arm > 30 degrees, previous surgery of the affected shoulder, extrinsic causes of shoulder pain, history of severe trauma of the shoulder in the previous two years (e.g. fracture, luxation)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Arm support system Gowing
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 26496
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	application Nederlands Trial Register pending
CCMO	NL55711.042.15
OMON	NL-OMON26496