Dynamic consequences of arm support on shoulder function

Gepubliceerd: 01-03-2016 Laatst bijgewerkt: 19-03-2025

NA

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26496

Bron
Nationaal Trial Register

Aandoening

arm support
shoulder function
neuromuscular disease
arm ondersteuning
schouderfunctie
neuromusculaire aandoeningen
FSHD

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: STW (Stichting Technologie en Wetenschap)
Focal Meditech BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measures are shoulder loads and muscular effort

Toelichting onderzoek

Achtergrond van het onderzoek

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. Shoulder loads estimated with musculoskeletal simulations, shoulder stability and

associated muscular effort of up to 15 subjects with FSHD and up to 15 healthy controls will be

compared during the performance of standardized upper extremity tasks with and without an arm

support system. In preparation of transferring to home measurements, movements will be recorded

with a portable inertial magnetic measurement system in addition to traditional, laboratory bound

motion capture equipment and EMG. The feasibility and validity of shoulder loads estimated with

musculoskeletal simulations based on inertial magnetic data will be established.

Question1: How are muscular efforts of persons with FSHD and healthy controls related to shoulder

loads and stability while per forming standardized upper extremity tasks with and without an arm

support?

Hypothesis1: Activity changes in the muscles involved in scapular stability depend on the magnitude

and direction of the shoulder load generated by the arm support. The activity onset of the muscles

involved in scapular mobility will be affected by the arm support, while coordination strategies of

these muscles will remain unaltered.

Question2: What is the feasibility and validity of musculoskeletal simulated shoulder load predictions

based on inertial magnetic data.

Hypothesis2: Biomechanical outcome parameters from musculoskeletal simulations based on inertial

magnetic data are expected to be similar to simulations based on Optotraks' position data.

Doel van het onderzoek

NA

Onderzoeksopzet

One session, in which kinematics, muscular effort (% EMG) and inertial magnetic data will be collected.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Healthy adults:

o Men and women, aged between 18-75 years

o Able to read/understand Dutch

o Able to give written informed consent

- Adults with FSHD:

o Men and women, aged between 18-75 years

o Able to read/understand Dutch

o Able to give written informed consent

o Able to transfer from wheelchair to chair with side- and lower back-rest

o Brooke scale 3 or 4 (3 of both)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Healthy adults:

o Diagnosed pathologies that could interfere with the measurement results.

o Presence of pain in the shoulder.

o History of severe trauma of the shoulder within the previous two years (e.g. fracture, luxation).

o Prior experience in using the Gowing arm support.

- Adults with FSHD:

o Comorbidities that could interfere with the measurement results.

o Incapable of abducting or elevating (anteflexion) the affected arm > 30 degrees.

o Previous surgery of the affected shoulder.

o Extrinsic causes of shoulder pain.

o History of severe trauma of the shoulder within the previous two years (e.g. fracture, luxation).

o Prior experience in using the Gowing arm support

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over

Controle: Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-03-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46136
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5564
NTR-old	NTR5685
CCMO	NL55711.042.15
OMON	NL-OMON46136

Resultaten