

# Dynamic consequences of arm support on shoulder function

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26496

### Source

NTR

### Health condition

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

## Sponsors and support

**Primary sponsor:** University Medical Center Groningen

**Source(s) of monetary or material Support:** STW (Stichting Technologie en Wetenschap)  
Focal Meditech BV

## Intervention

## Outcome measures

### Primary outcome

The primary outcome measures are shoulder loads and muscular effort

## Secondary outcome

The secondary outcome measure is shoulder load calculated from inertial magnetic measurements

## Study description

### Background summary

#### 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 performing 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.

## **Study objective**

NA

## **Study design**

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

## **Intervention**

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.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- 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)

## Exclusion criteria

### - 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

## Study design

### Design

Study type: Observational non invasive

Intervention model: Crossover

**Control:** Active

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 01-04-2016  
Enrollment: 30  
Type: Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 01-03-2016  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46136  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

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

## Study results