Determining Exercise Tolerance using an EMG Cycle Test in patients with FSHD

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Gaining an objective insight in muscle fatigue during exercise for patients with FSHD by 1. comparing the timing of change in sEMG amplitude and sEMG median frequency, to gas exchange variables, heart rate, work load and blood lactate levels during...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON44203

Source
ToetsingOnline

Brief title
DETECT-FSHD

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
Facioscapulohumeral Muscular Dystrophy, Landouzy Dejerine

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: stichting afdeling Revalidatie Radboudumc

Intervention

Keyword: EMG, Exercise tolerance, FSHD, Outcome measure

Outcome measures

Primary outcome

sEMG amplitude

sEMG median frequency

Secondary outcome

gas variables (spirometry)

lactate, workload, heart rate

ECG

blood lactate levels

blood pressure

saturation

Borg scale

Study description

Background summary

More than 60% of patients with Facioscapulohumeral muscular dystrophy (FSHD) experiences severe fatigue. Increasing the level of physical inactivity by aerobic exercises or cognitive behavioural therapy leads to a lower level of fatigue and a deceleration of the increase of fatty infiltration of upper leg muscles in these patients. However, the effect of both therapies on exercise tolerance is unknown. Current outcome measures for exercise tolerance focus on the cardiovascular system by the use of ergospirometry. For patients with FSHD, muscle fatigue generally is the limiting factor during exercise. One possible non-invasive alternative to objectively measure muscle fatigue on the (neuro)muscular level could be the use of surface electromyography (sEMG).

Study objective

Gaining an objective insight in muscle fatigue during exercise for patients with FSHD by
1. comparing the timing of change in sEMG amplitude and sEMG median frequency, to gas exchange variables, heart rate, work load and blood lactate levels during an incremental cycle test
2. comparing the relative timing of change in sEMG amplitude and sEMG median frequency in patients with FSHD with the relative timing of change in sEMG amplitude and sEMG median frequency in healthy subjects

Study design

Explorative cross-sectional proof of concept pilot study

Study burden and risks

The burden and risks associated with participation are neglectable. The task that need to be performed is safely performed by healthy subjects and FSHD patients before. CE marked equipment is used.

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

- aged 18 years and older
- being able to read and understand the Dutch language
- mentally competent
- being able to cycle at least 8 minutes on a bicycle ergometer

Exclusion criteria

- pregnancy
- cognitive impairment
- disabling co-morbidity interfering with the cycle test
- contraindications to Exercise Stress Testing according to the guidelines of the American Heart Association

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2018

Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2018
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	NL62686.091.17