Aerobic Muscle Capacity in PPS.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20931

Source
NTR

Health condition

Postpoliomyelitis Syndrome, Neuromuscular diseases, Fatigue, Skeletal muscle, Aerobic capacity

Postpoliomyelitis Syndroom, Neuromusculaire aandoeningen, Vermoeidheid, (Skelet)spieren, Aerobe inspanning

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Rehabiliation
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development, Prinses Beatrix Fonds

Intervention

Outcome measures

Primary outcome

Variables for peripheral muscle properties include:

1. Critical torque (Nm);

2. Fatigue index (%);

3. Rate of torque development/decline (%)These will be determined with maximal voluntary contractions and (submaximal) electrically evoked contractions of the knee extensor muscles.

Variables for aerobic exercise capacity include:

1. VO2peak (ml/min/kg);

2. VO2 at anaerobic threshold (ml/min/kg);

3. Power output at anaerobic threshold (W);

4. Heart rate at anaerobic threshold (bpm).

These will be determined during graded exercise testing on a cycle ergometer.

Secondary outcome

Multiple measures of muscle strength and muscle activation will be determined:

1. Maximal Voluntary Contraction (MVC) (Nm);

2. Voluntary Activation (%);

3. Peripheral fatigue and Central fatigue (%).

Study description

Background summary

Rationale:

Patients who suffer from Postpoliomyelitis Syndrome (PPS) generally report severe fatigue, and a decline in their functional abilities and health-related quality of life, as their main problems. It is very well conceivable that these problems are, in part, caused by the reduced exercise capacity most patients with PPS have. This reduced exercise capacity is primarily caused by a reduction in muscle mass, and furthermore by a deterioration of intrinsic muscle properties of the (mostly lower limb) muscles and circulation. However, despite the assumption that, apart from muscle fiber degeneration, loss of aerobic muscle capacity and/or reduced peripheral circulation as a result of physical deconditioning will lead to early muscle fatigue and thereby limit exercise capacity in patients with PPS, no studies exist that have demonstrated indisputable evidence. Therefore, an important objective is to obtain

more information on peripheral muscle properties that can account for the reduced exercise capacity in patients with PPS.

Furthermore, clear guidelines to determine the target intensity for aerobic training in patients with PPS are lacking. To develop better recommendations, thereby preventing issues like under- or overtraining, insight in the aerobic capacity of these patients is needed. However, conventional ways to determine aerobic exercise capacity in healthy subjects (by maximal exercise testing) can not be applied to PPS patients due to the risk of overload. Furthermore, since determination of aerobic exercise capacity by submaximal exercise testing (by establishing the anaerobic threshold) is not possible in 1/3 of the patients, this project aims to develop an alternative method for determining aerobic exercise capacity in patients with PPS.

Objective:

To obtain more information on peripheral muscle properties that can account for the reduced exercise capacity in patients with PPS compared to healthy subjects, and to develop an alternative method for determining aerobic exercise capacity in patients with PPS.

Study design:

A cross-sectional study will be conducted at the outpatient clinic of the Department of Rehabilitation at the Academic Medical Center (AMC) in Amsterdam. The study will be performed in collaboration with the Faculty of Human Movement Sciences (VU University) in Amsterdam.

Study population:

30 patients with PPS and 30 able-bodied control subjects, matched for age, physical ectivity level, gender, body weight and height will be recruited.

Main study parameters/endpoints:

Variables for peripheral muscle properties include critical torque, fatigue index and slope of torque decline. These will be determined with maximal voluntary contractions and (submaximal) electrically evoked contractions of the knee extensor muscles.

Variables for aerobic exercise capacity include power output, VO2 and heart rate at anaerobic threshold. These will be determined during graded exercise testing on a cycle ergometer.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

One visit to the Academic Medical Centre in Amsterdam and three visits to the VU University in Amsterdam will be required for patients. Control subjects will be asked to visit the VU University once more. The duration of each examination will be approximately 1 hour.

The risks related to the functional tests are considered minimal. Determination of the fatigue resistance can cause temporary muscle soreness (the result of overexertion of already weakened muscles), but are not known or expected to have any long term negative effects. While there are no direct benefits to the participants, the findings can be used in the clinical setting to more accurately set target intensity for aerobic training in patients with PPS (and possibly other neuromuscular disorders as well). This can guide choices of treatment for a PPS patient and encourage further research into new evidence based treatment.

Study objective

Research questions and accompanying hypotheses:

1. Is there a difference in fatigue resistance of the knee extensor muscles between patients with PPS and able-bodied control subjects and is this related to aerobic capacity?

Hypothesis: It is hypothesized that fatigue resistance of the knee extensor muscles is lower in patients with PPS, compared to able-bodied control subjects, and that this difference is related to differences in aerobic capacity.

2. What is the reproducibility of the critical torque of the knee extensor muscles (as obtained with the STIM protocol) in patients with PPS and able-bodied control subjects?

Hypothesis: Because muscles are stimulated electrically (and central factors as activation and/ or motivation thus will not play a role), it is hypothesized that the reproducibility of the critical torque measures will be good in both groups.

3. Is there a correlation between critical torque of the knee extensor muscles, as obtained with repeated stimulated contractions (STIM protocol) and the critical torque as obtained with

repeated maximal voluntary contractions (Burnley protocol) in able-bodied subjects?
Hypothesis: It is hypothesized that critical torque measures, as obtained with electrical muscle stimulation will be related to critical torque measures obtained with maximal voluntary contractions, therewith giving valid information on the aerobic muscle capacity.

4. Is there a correlation between the critical torque of the knee extensor muscles (as obtained with the STIM protocol) and the aerobic exercise capacity (i.e. anaerobic threshold) in patients with PPS and able-bodied control subjects?

Hypothesis: Since the critical torque is defined as the upper limit of exercise intensity that can be sustained aerobically and without fatigue, it is hypothesized that this is related to the anaerobic threshold, therewith giving information the aerobic exercise capacity in patients with PPS and able-bodied subjects. Hence, this may be used for determination of the aerobic exercise capacity in patients with PPS, in which the anaerobic threshold can not be determined (1/3 of the patients).

Study design

1. October 2010: Testing research equipment, setting up databases, selection eligible participants;

2. November 2010 – December 2011: Data collection and data entry;

3. January 2012 – December 2012: Statistical analysis and writing scientific articles.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Patients: Diagnosis of PPS according to the criteria of March of Dimes (2000)*:

1. A confirmed history of paralytic poliomyelitis characterized by an acute illness with fever and a usually asymmetrically distributed, flaccid paresis of a varying number of muscle groups. Evidence of motor neuron loss on neurological examination with signs of residual weakness, atrophy, loss of tendon reflexes and intact sensation;

2. A period of partial or complete functional recovery after acute paralytic poliomyelitis, followed by an interval (usually 15 years or more) of stable neurologic function;

3. Gradual or sudden onset of progressive and persistent new muscle weakness or abnormal muscle fatigability (decreased endurance), with or without generalized fatigue, muscle atrophy, or muscle and joint pain. Symptoms persist for at least a year;

4. No other medical diagnosis to explain the symptoms.

Control subjects:

Healthy volunteers, matched for age, physical activity level, gender, body weigth and height.

*March of Dimes Birth Defects Foundation. Identifying Best Practices in Diagnosis & Care Warm Springs, GA: March of Dimes International Conference on Post-Polio Syndrome. 2000.

Exclusion criteria

Patients and control subjects:

1. Disabling co-morbidity influencing the outcome parameters (including cardiopulmonary disease like chest pain, arrhythmia, pacemaker, cardiac surgery, severe dyspnoea d’effort or emphysema, epileptic seizures, poorly regulated diabetes mellitus);

2. Inability to cycle on a bicycle ergometer;

3. Inability to activate the knee extensor muscles.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2010
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	09-11-2010
Application type:	First submission

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
NTR-new	NL2479
NTR-old	NTR2595
Other	METC Academic Medical Center Amsterdam : 10/193
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A