# 'Aerobic muscle capacity in patients with Postpoliomyelitis Syndrome'

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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...

Ethical review	Approved WMO	
Status	Pending	
Health condition type	Neuromuscular disorders	
Study type	Observational non invasive	

# Summary

### ID

NL-OMON34578

**Source** ToetsingOnline

**Brief title** 'Aerobic muscle capacity in patients with PPS'

### Condition

• Neuromuscular disorders

**Synonym** Postpoliomyelitis Syndrome, PPS

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

### Intervention

Keyword: aerobic exercise, fatigue, muscle, postpoliomyelitis syndrome, skeletal

### **Outcome measures**

#### **Primary outcome**

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.

#### Secondary outcome

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

Maximal Voluntary Contraction (MVC), Voluntary Activation (VA), Peripheral

Fatigue and Central Fatigue.

# **Study description**

#### **Background summary**

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 (Nollet et al, 1999). It is very well conceivable that these problems are, in part, caused by the reduced exercise capacity most patients with PPS have (Nollet et al., 2001; Stanghelle et al., 1993). This reduced exercise capacity is likely to be primarily caused by deterioration of intrinsic/local muscle properties of the (mostly lower limb) muscles and circulation (Kilmer, 2002; Miller, 2002; Willen et al., 1999). 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 guideline recommendations to determine the target intensity for aerobic training in patients with PPS are lacking. To develop better guideline recommendations, thereby preventing issues like under- or overtraining, it is necessary to gain insight into the aerobic capacity of these patients. However, since 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, this project aims to develop an alternative method for determining aerobic capacity in patients with PPS.

#### **Study 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 burden and risks

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 the each examination will be approximately 1 hour.

The risks related to the functional tests are considered minimal and a physician will be present during the testing. 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 options.

# 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**

Patients:

- Diagnosis of PPS according to the criteria of March of Dimes (2000)\*:;a. 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.b. 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.

c. 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. d. No other medical diagnosis to explain the symptoms. (see p. 14-15 of the protocol);Control Subjects:

- Healthy volunteers, matched for age, 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:

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

# Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	60
Туре:	Anticipated

# **Ethics review**

Approved WMO Application type: Review commission:

First submission METC Amsterdam UMC

# **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** CCMO **ID** NL33034.018.10