*The reproducibility of the energy cost of walking test and the 6-minute walk test to assess the physical strain of walking in post-poliomyelitis syndrome patients'

Published: 21-02-2012
Last updated: 19-03-2025

1. To determine the reproducibility of the ECWT and the 6MWT to assess the physical strain of walking in patients with PPS and in healthy control subjects.2. To evaluate the one-year course of the physical strain of walking among patients with PPS...

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

Summary

ID

NL-OMON41241

Source
ToetsingOnline

Brief title
Physical strain of walking 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

Intervention

Keyword: physical strain, postpoliomyelitis syndrome, reproducibility of results, walking

Outcome measures

Primary outcome

The primary study parameters are speed (in m/min), the 6-minute walking distance (6MWD in m), heart rate (HR in b/min), and EC walking (in J/kg/m), as measured with the ECWT. From the 6MWT, speed, 6MWD, and HR will be calculated.

Secondary outcome

Secondary study parameters are the patient*s perceived exertion score (as measured with the Borg scale), and the patient*s perceived fatigue (as measured with the FSS, DEFS and CIS).

FSS = Fatigue Severity Scale

DEFS = Dutch Exertion Fatigue Scale

CIS = Checklist Individual Strength

Study description

Background summary

Survivors of poliomyelitis may develop new neuromuscular symptoms later on in life, including new muscle weakness, fatigue and muscle pain. These new symptoms are referred to as the postpoliomyelitis syndrome (PPS). PPS may cause increasing difficulties with mobility, by a reduced walking speed and an increased physical strain of walking, which can be up to 3 times higher, compared to healthy controls. In the literature, two distinct walking capacity tests are commonly used to assess the physical strain of walking, including the 6-minute walk test (6MWT) and the energy cost of walking test (ECWT). However,

the reproducibility of both these tests in PPS patients has never been compared.

Study objective

1. To determine the reproducibility of the ECWT and the 6MWT to assess the physical strain of walking in patients with PPS and in healthy control subjects.

2. To evaluate the one-year course of the physical strain of walking among patients with PPS and healthy control subjects, as quantified with the ECWT and the 6MWT.

3. To determine the relationship between the physical strain of walking and perceived fatigue in patients with PPS.

Study design

An intra-rater (i.e. between occasions) test-retest reproducibility study will be conducted at the outpatient clinic of the department of Rehabilitation in the Academic Medical Center in Amsterdam.

Study burden and risks

Measurements with the ECWT and 6MWT will be performed twice within 2 weeks (at T0 = 0 weeks (test), at T1 = 2 weeks (retest)). The duration of these tests will be approximately 45 minutes. Furthermore, at the first visit the patient is asked to fill in three fatigue questionnaires (FSS, DEFS, and CISr20). The duration for completing these questionnaires is 10 minutes. Possible medical risks related to performing the tests are considered minimal. Also, the load for the patients is low; per visit two sub-maximal walking tests will be performed (comparable to walking in daily-life), with bouts of (seated) rest in between the different parts of the experiment.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
-a confirmed history of paralytic poliomyelitis
-capable of walking independently for more than 150m without any supportive devices
-aged between 18 and 75 years;Control subjects:
-healthy volunteers, matched for age, gender, body weight and height.

Exclusion criteria

Patients en control subjects:
-cognitive impairment
-insufficient mastery of the Dutch language
-impairments that could contra indicate performing a 6-minute walk test

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-05-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	21-02-2012
Application type:	First submission
Review commission:	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

ID: 22236
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL39153.018.11
OMON	NL-OMON22236