Physical strain of walking in patients with PPS.

No registrations found.

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

Summary

ID

NL-OMON22236

Source
NTR

Health condition

Poliomyelitis, postpoliomyelitis syndrome, physical functioning, Energy cost of walking, Reproducibility

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam
Source(s) of monetary or material Support: Initiator (AMC)

Intervention

Outcome measures

Primary outcome

1. From the energy cost (EC) of walking test: speed (m/min), 6-minute walking distance (6MWD [m]), heart rate (HR [b/min]),and EC walking (J/kg/m);

2. From the 6-minute walk test (6MWT): speed (m/min), 6MWD (m), and HR (b/min).

Secondary outcome

1. From the Borg scale: the RPE score;

2. From the Checklist Individual Strength: the CISr20-fatigue score;

3. From the Fatigue Severity Scale (FSS): the FSS score;

4. From the Dutch Exertion Fatigue Scale (DEFS); the DEFS score.

Study description

Background summary

BACKGROUND:

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.

OBJECTIVES:

To determine the reproducibility of the ECWT and the 6MWT for assessing the physical strain of walking in patients with PPS and in healthy control subjects; 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.

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 POPULATION:

Forty patients with PPS (age 18-75 years) who are capable of walking independently for more than 150m without any supportive devices are eligible, as well as 40 age-matched healthy controls.

STUDY PARAMETERS:

The primary study parameters are speed (in m/min), 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 study parameters are the patient's perceived exertion score (as measured with the Borg scale), and the patient's perceived fatigue score (as measured with the CISr20, the fatigue severity scale (FSS), and the Dutch Exertion Fatigue Scale (DEFS)).

Measurements with the ECWT and the 6MWT will be performed three times within one year (at T1 = 0 weeks (test), at T2 = 2 weeks (retest) and at T3 = 12 months (1-year follow-up)). 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 (CISr20, FSS and DEFS). The duration for completing these questionnaires is 10 minutes.

STATISTICAL ANALYSIS:

This will include descriptive and correlation statistics for all measurements; reproducibility statistics based on the T1 and T2 measurements; and paired samples t-tests between the mean of measurements at T1 and T2 and measurements at T3.

Study objective

1. To determine the reproducibility of the energy cost of walking test (ECWT) and the 6-minute walk test (6MWT) for assessing the physical strain of walking in patients with postpoliomyelitis syndrome (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

1. May 2012 – May 2014: Recruitment of participants and baseline measurements (T1);

2. May 2012 – July 2014: Follow up measurements (T2-T3);

3. May 2012 – July 2014: Data-analysis;

4. May 2014 – December 2014: Statistical analysis;

5. November 2014 – May 2015: Writing of scientific articles.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

1. A confirmed history of paralytic poliomyelitis;

2. Capable of walking independently for more than 150m with or without any supportive devices;

3. Aged between 18 and 75 years.

Healthy controls:

1. Capable of walking independently for more than 150m with or without any supportive devices;

2. Aged between 18 and 75 years.

Exclusion criteria

Patients and healthy controls:

1. Cognitive impairment;

2. Insufficient mastery of the Dutch language;

3. Impairments that could contra indicate performing a 6-minute walk test.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-05-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion
Date: 08-05-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41241
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3273
NTR-old	NTR3426
CCMO	NL39153.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41241

Study results

Summary results
N/A