Physical strain of walking in patients with PPS.

Gepubliceerd: 08-05-2012 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22236

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: Initiator (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Dept. of Rehabilitation
Academic Medical Center (AMC)
P.O. Box 22660
Merel Brehm
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667596

Wetenschappelijk

Dept. of Rehabilitation
Academic Medical Center (AMC)
P.O. Box 22660
Merel Brehm
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667596

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-05-2012
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41241
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A