Determinants of success of a stance-control-KAFO in former polio patients with quadriceps weakness.

Published: 12-09-2006
Last updated: 10-05-2024

The aim of the present study is two-fold: 1) To do a survey of patients who have been prescribed a SC-KAFO in the outpatient clinic and evaluate the indication of prescription, compliance, experience and motives for (non) use of the SC-KAFO. 2) To...

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

Summary

ID

NL-OMON30315

Source
ToetsingOnline

Brief title
The effect of the stance-control KAFO on walking.

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
late effects of poliomyelitis, post-polio syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: energy expenditure, orthotic devices, Poliomyelitis, walking

Outcome measures

Primary outcome

Succesful use of the prescribed SC-KAFO in daily life.

Secondary outcome

1) The primary outcome is energy expenditure of walking: Energy cost

(O2/kg/meter) and oxygen uptake (O2/kg/min).

2) Spatio-temporal paramters of gait (velocity, cadence, step length, stride

length)

3) Kinematic and kinetic parameters of gait (joint angles and moments of the

ankle, knee and hip joint)

4) Muscle strength of the knie flexors and extensors

5) Comfort and experienced functioning with the prescribed SC-KAVO

6) Health related quality of life

Study description

Background summary

After about many years of neurological and functional stability, patients who suffered from polio earlier in life may develop late-onset neuromuscular symptoms, which are referred to as the post poliomyelitis syndrome (PPS). The symptoms include new muscle weakness, fatigue and joint and muscle pain. These new symptoms often cause difficulties with walking.
Because of quadriceps weakness, a common problem in PPS, many patients need an ankle and/or knee orthoses to improve walking. Until recently patients were given a knee-ankle-foot orthosis (KAFO) with locked knee hinge to assure stability during walking with paresis of the quadriceps. This leads to a compensational gait resulting in increased energy cost of walking. To reduce

the increased energy expenditure the *stance-control KAFO* (SC-KAFO) was designed. This design automatically (electromagnetically/mechanical) releases the knee to allow swing phase flexion while knee flexion is restricted during stance (locked knee joint), approximating to the natural gait. It is well known that the compliance to use assistive devices is not optimal, therefore it is important to investigate the determinants of succesful use of prescribed orthoses.
Improving physical functioning is one the main aims of rehabilitation treatment and improving walking ability is therefore an important aim in this patient group.

Study objective

The aim of the present study is two-fold: 1) To do a survey of patients who have been prescribed a SC-KAFO in the outpatient clinic and evaluate the indication of prescription, compliance, experience and motives for (non) use of the SC-KAFO. 2) To investigate the effect on walking using a SC-KAFO compared to walking with previously used orthotics and a KAFO with locked knee hinge. As potential determinants of succesful use of the SC-KAFO energy expenditure of walking, walking performance, biomechanical gait parameters, muscle strength and experience of using SC-KAFO will be measured.

Study design

A questionnaire survey and a non-randomized self-controlled trial.

Study burden and risks

Patients will attend the department of rehabilitation of the AMC twice. During these visits a short clinical examination will take place, two questionnaires will be completed, two different walking test (with the SC-KAVO and the old orthotic condition) will be performed. One of the walking tes will also be performed in a subgroup of patients with a KAFO with locked knee hinge. In addition, muscle strenght of the knee flexors and extensors will be measured. Walking with the old orhotic condition may cause more tiredness. The workload of the different test is possible if enough resting breakes are taken between the different tests.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9, Postbus 22660
1100 DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9, Postbus 22660
1100 DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Diagnosis of poliomyelitis, 2) prescribed with a stance-control_KAFO, 3) ability to walk 6 minutes, 4) age 18-70

Exclusion criteria

Co-morbidid disease that limits physical exercise tolerance or limits the patient in visiting the hospital to participate in the study protocol.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

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

No registrations found.

In other registers

Register	ID
CCMO	NL14143.018.06