An evaluation of gait and patient experience of two newly developed stance-control knee joints for custom-made KAFO*s, a pilot study.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON30641

Source
ToetsingOnline

Brief title
Evaluation of two new joints for SC-KAFO's.

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
quadriceps muscle paresis, quadriceps muscle weakness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Fior&Genz GmbH,Medische hulpmiddelen industrie

Intervention

Keyword: energy expenditure, orthotic device, quadriceps weakness, walking

Outcome measures

Primary outcome

The effective use in daily life of the two new sc-kafo's in patients with

quadriceps weakness.

Secondary outcome

1) Energy expenditure during walking: Oxygen cost per meter

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

3) Kinematic en kinetic parameters of gait (jiont angles en moments of the

ankle, knee, hip and trunk)

4) Comfort and experienced functioning with the new sc-kevo's.

Study description

Background summary

Knee-ankle-foot-orthoses (KAFO*s) are prescribed for individuals with significant weakness of the knee extensors. 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 compared to a locked knee hinge. To reduce the increased energy expenditure when using a KAFO the *stance-control KAFO* (SC-KAFO) was developed. These devices are designed to allow free flexion of the knee in swing, while providing full stability in stance by automatically locking on intitiation of the stance phase of gait. Recent advances in orthotic technology have led to the development of several new

stance-control knee joints. To optimize the effectiveness and use of newly designed assistive devices, thorough evaluation is of importance. Two recently developed new joints for custom made SC-KAFO*s with two different locking mechanisms, are objectively evaluated in this pilot study. Improving physical functioning is one of the main aims of rehabilitation treatment and improving walking ability is therefore an important aim in this patient group.

Study objective

The aim of this study is to investigate whether the new joints for the sc-kevo's can be effectively operated by the patient, and whether a minimal hip extensor strength is needed to operate the joints succesfully. Secondly, the effect of the new joints for the sc-kevo's on gait is evaluated and compared to walking in the old orthotic condition.

Study design

A cross-over (pilot) study.

Intervention

Walking with two new types of stance-control, knee-ankle-footortheses. Each new sc-kevo will be worn for a period of 4 weeks, at the end of this 4-week period the evaluation will take place by using questionnaires and performing walking tests.

Study burden and risks

Patients will attend the department of rehabilitation of the AMC 8 times. Five of these visits are for measuring, fitting and handing out of the new orthesis. Three of the visits are for the evaluation and gait assessemnts of the old and new orthosis. During the first assessment visit a short clinical examination will take plase. On each visit a questionnaire will be completed and walking tests will be performed.
Walking (in daily life) with the new orthoses may cause more tiredness in the beginning of using the new orthosis. The workload of the different tests is possible
if enough rest is taken between the different tests.

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

1) quadriceps muscle weakness, 2) Currently successful users of a KAFO with locked joint or a SC-KAFO, 3) ability to walk 6 minutes, 4) age 18-70

Exclusion criteria

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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2007
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Generic name:	Knee ankle foot orthosis
Registration:	Yes - CE intended use

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	NL16251.018.07