Precision orthotics: optimizing ankle foot orthoses to improve gait in neuromuscular diseases

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Ethical review	Approved WMO
Status	Completed
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON47047

Source
ToetsingOnline

Brief title
Optimizing of ankle foot orthoses in neuromuscular diseases

Condition

- Neuromuscular disorders

Synonym
flaccid paresis, muscle disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: ankle foot orhosis, neuromuscular disorders, treatment outcome, walking ability

Outcome measures

Primary outcome

The main study endpoint will be walking effort (ECW), which will be measured during a 6-minute walk test (6MWT) with simultaneous gas-analysis.

Secondary outcome

Secondary study endpoints will include: joint angles and net joint moments during gait (measured by 3D gait analysis); walking speed (assessed with a 6MWT); perceived physical functioning (assessed with the 36-Item Short-Form Health Survey questionnaire); perceived fatigue (measured with the Fatigue Severity Scale); daily step activity (measured with the StepWatch3TM Activity Monitor 3.0 + a motivation dairy); and satisfaction (evaluated on a 10-point Numeric Rating Scale). Additional endpoints will include isometric strength and passive stiffness characteristics of the calf muscles; visualization of the fiber architecture of the calf muscles, assessed with diffusion-tensor magnetic resonance imaging; the AFO stiffness and treatment adherence.

Study description

Background summary

Patients with paretic calf muscles due to neuromuscular diseases walk unstable at a reduced speed and an increased walking effort. To overcome these gait problems, a carbon-fiber ankle-foot orthosis (AFO) can be prescribed. This AFO acts as a spring with high resistance around the ankle, providing stability during stance and augmenting push-off by releasing stored energy. While both mechanisms aim to reduce walking effort, their effectiveness depends on the

stiffness of the AFO. This is a delicate issue: if the AFO is too stiff, it will impede push-off, while a too compliant AFO won*t provide stability. Optimal AFO stiffness is key to the energetic benefit that can be obtained from it, and depends on patient characteristics. However, its relationship with the most favorable AFO stiffness that maximally reduces walking effort is unclear. This lack of knowledge limits optimal AFO provision in patients with neuromuscular diseases.

Study objective

To determine whether AFOs optimized for stiffness in patients with calf muscle weakness are superior to standard AFOs in reducing walking effort, as measured by energy cost of walking (ECW, in Jkg-1m-1), and 2) to build a model to predict required AFO stiffness to maximally reduce walking effort.

Study design

The study design includes a nonrandomized self-controlled experimental study, with three repeated measurements, i.e. at baseline, walking with the current old AFO (pre-treatment, T1); directly after supplying the new AFO in each of five stiffness (K) configurations (T2K1 -T2K5); and after a 3-month follow-up (T3Kopt), walking with the selected optimal AFO configuration. The total duration of the study will be approximately 18-20 weeks. The study will be performed at the Department of Rehabilitation of the Academic Medical Center Amsterdam.

Intervention

Participants will receive a new AFO that will be adjusted into five stiffness configurations (range: very flexible - very stiff). For each individual patient, the optimal AFO configuration will be selected, which will be evaluated 12 weeks later.

Study burden and risks

Visits for baseline measurements (n=3, ±1 to 2.5 hours per visit) will be scheduled simultaneously with the regular consultancies for AFO treatment (casting and fitting), to limit the number of visits to the medical centre. Optimization measurements at T2 (n=2 visits) will be performed for five AFO stiffness configurations (±2.5 hours per visit). The 3-month follow up measurement at T3 (n=1 visit) will be performed for the selected optimal AFO (±2.5 hours).

Measurements are non-invasive. It is possible that the orthosis causes pressure sores or pain during walking, which is common in orthotic care. The risk of pain will be marginal and subjects can quit the measurements if pain occurs.

Risks for the subjects undergoing a MRI examination are also minimal, provided precautions have been made to prevent examining individuals with contraindications. For this purpose, the routine MRI contra indications form of the AMC will be used.

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

-age between 18 and 80 years;
-weakness of the calf muscles (i.e. a MRC score <5 or unable to perform >3 heel rises);
-using an AFO or orthopedic boot (one or both sided);
-able to walk for 5 minutes, with or without walking aids;
-able to walk for 10m barefoot without assistive devices.

Exclusion criteria

-presence of pes equinus under weight-bearing (dorsiflexion * 0º);
-severe deformity of the ankle/foot that cannot be fitted with a custom-made AFO;
-severe weakness of the upper legs requiring a knee-ankle-foot orthosis;
-body weight > 120 kg.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-07-2015
Enrollment:	60
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	18-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2017
Application type:	Amendment
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: 22379
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50511.018.14
OMON	NL-OMON22379