Optimizing ankle foot orthoses in neuromuscular diseases

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22379

Source
Nationaal Trial Register

Brief title
PROOF-AFO

Health condition

Neuromuscular diseases (neuromusculaire aandoeningen); calf muscle weakness (kuitspierzwakte); ankle foot orthosis, AFO (enkel voet orthese, EVO); gait pattern (gangpatroon); walking effort (energieverbruik); stiffness (stijfheid);

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds
OIM Noppe orthopedie
Otto Bock Healthcare

Intervention

Outcome measures

Primary outcome

The primary outcome will be walking energy cost (in J/kg/m), which will be measured during a

6-minute walk test (6MWT) at comfortable speed with simultaneous gas-analysis. Gas-analysis will be measured using the portable Cosmed K4B2 system.

Secondary outcome

Secondary outcomes will include joint angles and net joint moments during gait, walking speed, perceived physical functioning, perceived fatigue, daily step activity and AFO satisfaction.

-Joint angles and net joint moments during gait will be measured with a VICON 8-camera motion analysis system and four force plates. Patients are asked to walk along a 10 meter walkway until three successful trials are recorded to calculate gait biomechanics.

-Walking speed (m•min-1) will be measured during a 6MWT at comfortable speed.

-Perceived physical functioning will be measured using physical functioning scale of the Medical Outcome Study 36-Item Short-Form Health Survey (SF36).

-Perceived fatigue will be assessed with the Fatigue Severity Scale (FSS).

-Daily step activity will be measured using the StepWatch3TM Activity Monitor 3.0, which is an ankle worn pedometer that that measures the average amount of steps per minute over a broad spectrum of step cadences. For adequate interpretation of the data, subjects will be asked to note their activity program during the day in a diary. Furthermore, a temperature sensitive device, called ODM, will be placed into the AFO to check the percentage of the number of steps people take with the AFO.

-AFO satisfaction is measured using a 10-point numeric rating scale. Questions about stability, intensity and performance during walking will be assessed. Furthermore, satisfaction with the outcome will be evaluated using a five-level Likert Scale.

As additional outcomes, the stiffness properties of the patient’s current (old) and new AFO will be measured. Furthermore, at baseline, anthropometrics, demographics, isometric muscle strength and passive stiffness characteristics of ankle plantar flexors will be assessed.

Study description

Study objective

Ankle foot orthoses (AFOs) of which the stiffness mode-of-action is optimized will be more effective in reducing the walking effort compared to standard AFOs. The optimal AFO stiffness at which walking effort is lowest will be determined by patient characteristics regarding anthropometrics, impairments and walking speed.

Study design

The total study duration will be 48 months. The first 6 months of the study will be used to train the research investigator and to involve the participating centers; from 6 to 30 months, patients will be recruited for the study and baseline assessments will be performed; and from 9 to 36 months, the follow up measurements will be performed. The final 12 months will be used for analyses, and addressing the main research questions.

Intervention

After inclusion, participants will be fitted with a new AFO. This AFO consists of a foot part, a calf casting and a replaceable carbon fiber spring. As such, stiffness of the AFO can be varied within the same orthosis. For each patient, five carbon fiber springs will be evaluated (ranging in stiffness from very flexible (K1) to very stiff (K5)), allowing the selection of the stiffness with the maximal benefit for a particular subject (i.e. with the greatest reduction in walking effort), referred to as the subject's optimal AFO. The effect of this optimal AFO will be evaluated 12 weeks later and compared to the patients current (old) AFO.

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Eligibility criteria

Inclusion criteria

- patients with non-spastic distal weakness of the calf muscles weakness (defined as an MRC score < 5 or unable to perform > 3 heel rises);

- age: between 18 and 80 years old;

- using an AFO or orthopedic boot (one or both sided);

- able to walk for 6 minutes with or without assistive device;

- able to walk for 10 m barefoot without assistive devices.

Exclusion criteria

- presence of pes equinus under weight-bearing (dorsiflexion < 0 degrees);

- severe deformity of the ankle/foot that cannot be fitted with an AFO;

- severe weakness of the upper legs requiring a knee-ankle-foot orthosis;

- body weight > 100 kg.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	37
Type:	Actual

Ethics review

Positive opinion
Date: 07-05-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47047
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5024
NTR-old	NTR5170
CCMO	NL50511.018.14
OMON	NL-OMON47047

Study results