Optimizing ankle foot orthoses in neuromuscular diseases

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22379

Bron
Nationaal Trial Register

Verkorte titel
PROOF-AFO

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Prinses Beatrix Spierfonds
OIM Noppe orthopedie
Otto Bock Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Meibergdreef 9

Niels F.J. Waterval
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 566 6915

Wetenschappelijk

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Amsterdam 1105 AZ
The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	37
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-05-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47047
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten