Patient preference to guide AFO prescription

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

Samenvatting

ID

NL-OMON28247

Bron
NTR

Verkorte titel
TBA

Aandoening

Neurological disorders

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: OIM Orthopedie and PPP-allowance by Health~Holland, Top Sector Life Sciences & Health

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

% agreement between patient’s preference and AFO efficacy in terms of L-test performance

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The majority of neurological patients with impaired gait can be prescribed with a carbon off-the-shelf ankle-foot orthoses (AFO) to improve their walking ability. A variety of these off-the-shelf AFOs is available on the market, claiming to store and release energy to enhance ankle push-off power. Clinical data on their effectiveness is however scarce, as well as clear criteria to support the prescription process. Yet, it is unclear for orthotists which AFO to choose for a specific patient. Consequently, the prescription process is ambiguous and choice for a specific AFO is often based on personal preference, knowledge of available products, clinical experience, and/or the patient's preference. Although the patient's preference has been measured before, it is unclear whether patients are able to choose the AFO that is most effective improving their walking ability. Hence, it is unknown whether an orthotist and/or physician can rely on the patient's own experience within their decision-making process.
Objective: To investigate whether the patient's preference during AFO-fitting could be guiding in the decision-making process of off-the-shelf carbon AFO prescription.
Study design: Explorative cross-sectional intervention study.
Study population: Neurological patients with reduced ankle push-off power using an off-the-shelf carbon AFO.
Intervention (if applicable): All patients receive two AFOs during AFO fitting. In the following 4 weeks, they use the two AFOs at home. In the first week they will use AFOa, in the second week AFOb and in weeks 3 and 4 the AFO of their own preference (which can vary day by day).
Main study parameters/endpoints: The primary outcome measure is % agreement between patient's preference and AFO efficacy in terms of L-test performance.

Doel van het onderzoek

It is expected that patients prefer the AFO with the best efficacy, and that the preference is reliable at the moment of AFO fitting.

Onderzoeksopzet

At baseline (T0), patients will perform a L-test with both AFOs, and their preference will be assessed. Afterwards, patients are sent home with both AFOs, and will be instructed to wear each AFO consecutively for one week (T1-AFOa and T1-AFOb – randomized order). After these two weeks, patients are allowed to wear the AFO according to their own preference for another two weeks (T1-AFOp). Within this period, patients are allowed to switch AFOs whenever they want. During T1, treatment adherence will be measured with a micro temperature sensor. After four weeks of wearing the AFOs, patients return to the Sint Maartenskliniek for final evaluation measurements, consisting of an L-test and 3D gait analysis during a 2-minute walk test (2MWT) and precision stepping task (PST) to assess AFO efficacy. Additionally, patient's preference will be assessed

Onderzoeksproduct en/of interventie

Two off-the-shelf carbon AFOs: i) Toe-OFF (AllardInt, Helsingborg, Sweden) and ii) Sprystep Max (Thuasne, Levallois-Perret, France).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >18 years old <80 years old
- Neurological disorders, such as stroke, MS, spinal cord injury
- At least 6 months post injury-onset to ensure a stable neurological condition
- Reduced ankle push-off power (clinically assessed by functional testing)
-

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Using orthopedic shoes in combination with AFO
- Receiving focal treatment for spasticity (e.g.with botulinum toxin) within 6 months
- Calf muscle hypertonia (Modified Ashworth scale (MAS) >2/5)
- Hip flexor and extensor weakness (MRC<4/5)

- Knee extensor weakness (MRC<4/5)
- Patient with neuropathic and/or orthopedic comorbidities that affect AFO efficacy
- Patient with cognitive impairment(s) not being able to follow instructions

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-10-2020
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8991
Ander register	METC Arnhem-Nijmegen : 2020-6926

Resultaten