Patient preference to guide AFO prescription

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28247

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Neurological disorders

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: OIM Orthopedie and PPP-allowance by Health~Holland, Top Sector Life Sciences & Health

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- % agreement between patient’s preference at baseline and at evaluation
- Relation between L-test performance and joint kinematics and kinetics
- % agreement between patient’s preference and AFO efficacy in terms of walking speed and gait adaptability
- % agreement between orthotist’s preference and AFO efficacy in terms of L-test performance, walking speed and gait adaptability
- Spatiotemporal parameters
- Joint kinematics and kinetics
- Shank-to-vertical angle (SVA)
- AFO stiffness
- AFO satisfaction score
- AFO adherence

Study description

Background summary

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.

Study objective

It is expected that patients prefer the AFO with the best efficacy, and that the preference is

reliable at the moment of AFO fitting.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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)

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Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2020
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-10-2020

Application type: First submission

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
NTR-new	NL8991
Other	METC Arnhem-Nijmegen : 2020-6926

Study results