The feasibility and validity of the ADJUST-AFO to determine the optimal orthotic stiffness: a proof-of-concept study

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

Summary

ID

NL-OMON53208

Source
ToetsingOnline

Brief title
The ADJUST-AFO to determine the optimal orthotic stiffness

Condition

- Neuromuscular disorders

Synonym
flaccid paresis; neuromuscular disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Health Holland;ZonMw,OIM Noordwijkerhout B.V.,Stichting Reade,Technische Universiteit Delft (TU Delft)

Intervention

Keyword: ADJUST-AFO, ankle-foot orthosis, Calf muscle weakness, optimal stiffness

Outcome measures

Primary outcome

In study 1, feasibility will be assessed as the ability to complete the ADJUST-AFO stiffness variation protocol without the necessity to stop due to pain, fatigue or discomfort measured on a 10-point numeric rating scale (NRS).

For study 2, the feasibility of the ADJUST-AFO in people with calf muscle weakness will be assessed with, as primary outcomes, the ability to complete the optimization procedure (similar to study 1) and the difference in selected optimal stiffness for walking energy cost minimization compared to the usual care method.

Secondary outcome

Secondary outcomes in study 1 include occurrence of possible pressure sores or other adverse events (assessed by the researcher).

Secondary outcomes in study 2 include: occurrence of possible pressure sores or other adverse events (assessed by the researcher) and walking energy cost with the optimal stiffness (absolute value, in J/kg/m), walking speed (in m/s), heart rate (b/min), perceived fatigue and gait kinematics between the usual care method and the ADJUST-AFO method over-ground. Additionally, satisfaction

with and time needed for the usual care optimization procedure and the

ADJUST-AFO procedure will be recorded.

Study description

Background summary

In many slowly progressive neuromuscular diseases, calf muscle strength declines over time, leading to walking problems such as instability and increased energy cost of walking. The mainstay of treatment to improve walking in these patients is the provision of an ankle-foot orthosis (AFO). The effect of an AFO on walking, particularly on energy cost, depends on its stiffness. To maximize treatment outcomes of AFOs, the stiffness needs to be individually optimized. Currently, this optimization process consists of multiple 6-minute walk tests with different AFOs to select the optimal stiffness, which is time-consuming (+/- 8 hours for all tests together) and demanding for patients. To shorten the optimization, we recently developed, within the Amsterdam UMC, an AFO of which the stiffness can be continuously altered while walking, the ADJUST-AFO, requiring one single walk test of 20 minutes to select to optimal stiffness (combined called AFO-ADJUST optimization procedure).

Study objective

Our study uses a two-step approach.

In the first step (study part 1), we will assess the feasibility of the ADJUST-AFO to measure the optimization parameter, walking energy cost, while changing the stiffness during 20 minutes walking in healthy individuals.

In the second step (study part 2), the objective is to determine the feasibility of the stiffness variation protocol and the concurrent validity of the ADJUST-AFO optimization procedure to select the optimal stiffness in people with neuromuscular diseases exhibiting calf muscle weakness, with the current usual care procedure as comparator.

Study design

A cross-sectional design will be used to assess the feasibility of the stiffness variation protocol (study 1).

For assessing the feasibility and concurrent validity of the ADJUST-AFO optimization procedure, a pre-post design will be used (study 2).

Intervention

Participants will undergo an AFO-stiffness optimization procedure with the ADJUST-AFO (in both study part 1 and part 2). The ADJUST-AFO is an orthotic device of which the stiffness can be altered during walking by moving a slider actuated by an on-board motor. During the procedure, participants will walk for approximately 20-minutes with the ADJUST-AFO. Simultaneously, energy cost of walking and gait biomechanics are recorded.

While walking overground, the AFO stiffness will be randomly changed every 3 minutes into the same five stiffness levels as applied in usual care (range 2.8 to 6.6 Nm/degree), and outcomes will be compared with the optimization procedure as currently used in clinical practice. In usual care, the stiffness is manually adjusted, and for each stiffness level, a 6-minute walking energy cost test and gait analysis is performed.

Study burden and risks

Participants in study 1 will visit the hospital twice, for approximately 2 hours per visit to perform the stiffness variation protocol. During the visit, the optimization will be performed on a treadmill, and if it is deemed safe, a second optimization will be performed over-ground on a separate day.

Participants in study 2 will have two hospital visits of approximately 2.5 to 3 hours per visit. During these visits, the optimal stiffness with the usual care procedure (visit 1) and with the ADJUST-AFO while walking over-ground (visit 2) will be determined. Possible discomfort in both study 1 and 2 may include muscle soreness, fatigue and physical discomfort due to walking with a new AFO.

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

For healthy subjects:
- age >=18 years;
- no history of lower leg injuries or diseases affecting the gait pattern.

For patients:
- age >=18 years;
- presence of uni- or bilateral calf muscle weakness as determined by a manual muscle test score <5 or unable to perform three consecutive heel-rises on 1 leg;
- estimated to be able to walk for 20 minutes with the ADJUST-AFO;
- indicated for a (new) stiffness-optimized dorsal leaf AFO.

Exclusion criteria

For healthy subjects:
- weight >120 kg;
- wearing a Cardiac Implantable Electronic Device (CIED).
- pregnancy

For patients:
- weight >120 kg;
- wearing a Cardiac Implantable Electronic Device (CIED);
- indication for a knee-ankle-foot orthosis;
- pes equines during standing, i.e. not able to achieve a neutral ankle angle during standing;
- pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2023
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	ADJUST-AFO
Registration:	No

Ethics review

Approved WMO Date:	20-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2025
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

No registrations found.

In other registers

Register	ID
CCMO	NL84470.018.23