Feasibility, functionality and comfort of a novel concept Ankle-Foot-Orthosis for equinus foot

Published: 19-12-2019
Last updated: 09-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON52812

Source
ToetsingOnline

Brief title
A novel AFO concept

Condition

- Muscle disorders
- Central nervous system vascular disorders

Synonym
equinus foot, spastic foot deformity

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiegeneeskunde
Source(s) of monetary or material Support: NWO,InteSpring BV,OIM orthopedie,

Noordwijkerhout, Nederland

Intervention

Keyword: ankle-foot-orthosis, equinus, stiffness, upper motor neuron disease (UMND)

Outcome measures

Primary outcome

Active RoM at single joint level and during gait are primary outcomes.

Secondary outcome

Comfort and walkability based on PROMs and from instrumented gait analysis are

secondary outcomes.

Study description

Background summary

A large population of UMND patients suffer from increased passive ankle joint stiffness and limited active range of motion (RoM) impairing their gait. In order to improve gait, current ankle-foot-orthoses (AFOs) counteract this so called equinus foot to neutral position by providing continuous stretch towards dorsiflexion. These AFOs further increase joint stiffness at the cost of active RoM. Therefore, we elaborated on a new AFO concept to compensate (instead of increase) the excessive passive ankle joint stiffness. We have now developed a first wearable prototype AFO based on this concept, to be tested in our clinical population of UMND patients.

Study objective

The objective of this study is to test the feasibility, functionality and comfort of the AFO as an aid to regain the active RoM of the ankle joint in UMND patients with equinus foot. Results of the study will be used to further optimize the AFO design and future study protocols.

Study design

Feasibility and functionality will be tested using a within-subject design at single joint level (i.e. ankle movement only) and at activity level (gait) for 6 conditions: (1) without AFO, (2) with the subject*s current AFO, (3-6) with

the new AFO at 4 levels of stiffness compensation from *no* to *full* compensation. Overall comfort will be assessed by patient reported outcome measures (PROMs).

Intervention

Application of the new AFO in single joint measurements using an instrumented ankle manipulator and during gait using standard instrumented gait analysis, electromyography (EMG) and accelerometry .

Study burden and risks

Subjects visit the LUMC laboratory one day to join the two types of measurements (single joint level and activity level) for an estimated 60 min. measurement for each type. First, the subjects have a short physical examination, fill in a 5 min. questionnaire and participate in the measurements on single joint level (ankle function experiment of 6 x 15 s for the 6 different conditions while the patients is in seated position). Second, after a break the subjects join the measurements at activity level (2 min. walk on a treadmill for each of the 6 conditions) and fill in a 5 min. questionnaire.

Note: In the case the treadmill is not ready to use for the first five patients, the measurements will be performed by a 5m walking test: Patients will be asked to walk back and forth along the walkway at comfortable speed for the 6 different conditions. The main outcome measure (active RoM) will be measured by an electro-goniometer (Delsys, CE-marked) at lower leg of the patients synchronized with the EMG system.

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) a. Chronic stroke phase (defined as first stroke > 6 months)
b. Traumatic Brain Injury (> 6 months)
c. Hypoxic Brain Injury (> 6 months)
d. Cerebral Palsy
e. Multiple Sclerosis (relapse free in the previous 3 months)
f. Chronic incomplete spinal cord injury (> 6 months, ASIA score C or D)
2) Spastic paresis of the triceps surea muscles of the right or left leg
a. MAS>=2 (n=5)
b. MAS not restricted (n=25)
3) Equinus or equinovarus foot deformity of the affected spastic side (as mentioned under criteria no. 2), defined as an increased passive ankle joint stiffness and limited active range of motion of the affected side compared to the non-affected side
4) Prescribed walking aid (orthotic shoes or AFO)

Exclusion criteria

1) Age < 18 years
2) Drop foot (tibialis paresis)
3) Surgical treatment on the affected leg for spastic paresis
4) Inability to walk (with or without walking aid)
5) Inability to understand measurement instructions

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Negative Stiffness Orthosis
Registration:	No

Ethics review

Approved WMO

Date:	19-12-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL64640.058.19