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

No registrations found.

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

Summary

ID

NL-OMON28947

Source NTR

Brief title A novel AFO concept

Health condition

Stroke

Sponsors and support

Primary sponsor: Leiden University Medical Centre **Source(s) of monetary or material Support:** NWO-TTW

Intervention

Outcome measures

Primary outcome

Active ankle RoM at single joint and activity level

Secondary outcome

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Study description

Background summary

A large population of stroke 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 stroke patients. We will test the feasibility, functionality and comfort of the AFO using a within-subject design (n=30) at single joint level (i.e. ankle movement only) and at activity level (gait) with the new AFO at different levels of stiffness compensation. Overall comfort will be assessed by patient reported outcome measures (PROMs). Results of the study will be used to further optimize the AFO design and future study protocols.

Study objective

Higher stiffness compensation leads to increased passive and active ankle dorsiflexion

Study design

One measurement

Intervention

new AFO

Contacts

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Eligibility criteria

Inclusion criteria

Chronic stroke phase (defined as first stroke > 6 months); Spastic paresis of the Triceps Surae muscles of the left or right leg; Equinus or equinovarus foot deformity of the affected side defined as increased passive ankle joint stiffness and limited active RoM of the affected side compared to the non-affected side; Prescribed walking aid (orthotic shoes or AFO)

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-02-2021
Enrollment:	30
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date: Application type:

27-01-2020 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 NTR-new Other **ID** NL8358 METC LDD : P19.063

Study results