

Evaluation of a smart ankle foot orthosis

No registrations found.

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

Summary

ID

NL-OMON28390

Source

NTR

Brief title

Evaluation of a smart ankle foot orthosis

Health condition

Patients with paretic ankle muscles often use ankle foot orthosis (AFO) to improve walking. However, current AFOs also prevent ankle range of motion (ROM) and diminishes intact ankle muscle activity, thereby hampering the execution of activities in which ankle ROM is needed. Examples of such activities are level walking, hill locomotion, stair locomotion and standing up from/ sitting down on a chair. A smart AFO was designed to take over impaired ankle muscle activity and allow normal ankle ROM during level walking and during the execution of specific activities.

Keywords:

paretic ankle muscles, ankle range of motion, ankle foot orthosis (AFO), activities, walking

NL:

parese, enkel, enkel voet orthese (EVO), bewegingsuitslag van de enkel, activiteiten, lopen

Sponsors and support

Primary sponsor: Research center SPRINT and the University Medical Center Groningen

Source(s) of monetary or material Support: University Medical Center Groningen and the SNN (grant number T1015), the alliance of Northern Netherlands.

Intervention

Outcome measures

Primary outcome

During level and hill walking (7° inclination and 7° declination), measured with the GRAIL in Beatrixoord Haren:

a. Heel rocker:

i. Angular velocity of the ankle

ii. Ankle moment

iii. Ankle motion

iv. Ankle power

v. Duration of the heel rocker

b. Ankle rocker:

i. Ankle motion

ii. Ankle moment

iii. Ankle power

iv. Duration of the ankle rocker

c. Forefoot rocker:

i. Ankle motion

ii. Ankle moment

iii. Ankle power

iii. Duration of the forefoot rocker

d. Swing phase:

i. Ankle motion

ii. Duration of the swing phase

Time to perform activities, measured with a stopwatch:

- Timed Up and Go Test
- Timed three steps Stairs Ascent Test
- Timed three steps Stairs Descent Test
- Five Times Sit To Stand Test

Subject experience with the AFOs and suggestions for improvement measured with a self-developed questionnaire.

Secondary outcome

Knee and hip kinetics and kinematics, measured with the GRAIL in Beatrixoord Haren.

Study description

Background summary

Rationale: Patients with paretic ankle muscles often use ankle foot orthosis (AFO) to improve walking. However, current AFOs also prevent ankle range of motion (ROM) and diminishes intact ankle muscle activity, thereby hampering the execution of activities in which ankle ROM is needed. Examples of such activities are level walking, hill locomotion, stair locomotion and standing up from/ sitting down on a chair. A smart AFO was designed to take over impaired ankle muscle activity and allow normal ankle ROM during level walking and during the execution of specific activities.

Objective: To evaluate if the smart AFO provides adequate ankle moments and allows normal ankle ROM during level walking and during the execution of specific activities.

Study design: Feasibility study with cross-over design and random sequence generation.

Study population: Ten adults with plantarflexor paresis with or without dorsiflexor paresis.

Interventions: (1) standardized shoes + smart AFO, (2) own shoes + own AFO.

Study parameters/endpoints: Ankle moments and motion during stance phase and ankle motion during swing phase of level and hill walking. Timed performance of the timed up and go test, timed up and down stairs and timed sit to stand test. Subject experiences with the orthotic devices will be measured using a self-developed questionnaire.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Only immediate effects of the orthotic devices will be measured. Time span for a subject will be 2:30hrs. Subjects will walk at a self-selected speed on a treadmill that is also used for regular training purposes. Besides level and hill walking (both on the same treadmill), subjects walk up and down a three steps standardized staircase and stand up

from/ sit down on a standardized chair. The smart AFO should improve both patients' gait and the execution of activities.

Study objective

To evaluate if the smart AFO provides adequate ankle moments and allows normal ankle range of motion during walking and to evaluate if the execution of activities improves when using the smart AFO.

Study design

1 day

Intervention

(1) standardized shoes + smart AFO, (2) own shoes + own AFO.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged ≥ 18 years
- Able to understand Dutch

- Plantar flexor paresis (MRC-scale ≤ 3) (MRC is muscle strength from 0-5)
- Able to walk for a minimum of 6 minutes with own orthosis with or without additional walking aids
- Shoe size between 36 and 46
- Unilateral or bilateral plantar flexor paresis
- Use of an AFO daily (minimum 2 hrs/day, 6 days/week)
- Minimum ankle ROM of 15° (0-5° dorsiflexion, 10-15° plantarflexion)
- K-level 2 and higher

Exclusion criteria

- Diabetes
- Spasticity of the lower extremity muscles
- Using additional lower extremity orthosis (excluding insoles)
- Unable to complete the tests (total 2:30hrs)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	27-05-2015

Enrollment: 10
Type: Anticipated

Ethics review

Positive opinion
Date: 28-05-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41761
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5106
NTR-old	NTR5238
CCMO	NL48904.042.14
OMON	NL-OMON41761

Study results