Gait and user experiences of the NEUROTRONIC SC-KAFO

No registrations found.

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

Summary

ID

NL-OMON20209

Source
NTR

Brief title
Neurotronic Study

Health condition

The study population consists of patients with (non-spastic) lower extremity muscle weakness, including the quadriceps muscle, which may result from a variety of neuromuscular disorders such as polyneuropathies, poliomyelitis, and muscular dystrophies.

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam The Netherlands
Source(s) of monetary or material Support: Fior & Gentz Orthopädietechnik and OIM orthopedie

Intervention

Outcome measures

Primary outcome

Knee-joint securing while walking under challenging conditions and walking energy cost at comfortable speed

Secondary outcome

Spatiotemporal parameters; joint angles and net joint moments during gait; and satisfaction and user experiences

Study description

Background summary

Rationale: People who have knee instability that is associated with weakness of knee extending muscle groups can be provided with a custom made stance control knee-ankle foot orthosis (SC-KAFO). These devices allow free knee flexion in swing, while providing full stability in stance by automatically locking on initiation of the stance phase of gait. Two commercially available locking mechanisms for SC-KAFOs are the E-MAG Active knee-joint (Otto Bock) and the NEURO TRONIC knee-joint (Fior & Gentz). Because the E-MAG Active knee-joint requires full extension of the knee in terminal swing to lock, versus the NEURO TRONIC knee-joint that can lock at any flexion angle of the knee and in every part of the swing phase, it is expected that the NEURO TRONIC knee-joint is more secure when walking under varying circumstances. Yet, stance control securing of both joint systems and the effects of the NEURO TRONIC SC-KAFO and E-MAG Active SC-KAFO on gait and user experiences have never been compared.

Objective: 1) To demonstrate superiority of the NEURO TRONIC SC-KAFO in stance control securing while walking under challenging conditions compared to the E-MAG Active SC-KAFO; and 2) to demonstrate superiority of the NEURO TRONIC SC-KAFO on walking energy cost, gait biomechanics and user experiences compared to the E-MAG Active SC-KAFO.

Study design: A prospective intervention study (pre-post design).

Study population: 10 patients aged 18 years and older who already use an E-MAG Active SC-KAFO for weakness of knee extending muscle groups will be recruited.

Intervention (if applicable): Participants will receive a new NEURO TRONIC SC-KAFO prescribed according to the physiological model technique.

Main study parameters/endpoints: For objective 1, the main study endpoint will be securing of the knee-joint while walking under challenging conditions, as measured during a perturbation walk test on the instrumented C-Mill treadmill. For objective 2, the main endpoint will be walking energy cost (measured with a 6-minute walk test at comfortable speed with simultaneous gas-analysis). Secondary endpoints include spatiotemporal

parameters and joint angles and net joint moments during gait (measured by a 3D gait analysis), and user experiences (measured with a questionnaire). Endpoints will be assessed at baseline (T0), and after 1 month (T1) and 3 months (T2) of using the NEURO TRONIC SC-KAFO permanent and without any complaints.

Study objective

It is expected that, compared to the E-MAG Active knee joint, the NEUROTRONIC knee-joint is more secure when walking under varying circumstances and thereby more effective in improving gait and patient satisfaction

Study design

Primary and secondary outcomes will be assessed pre-treatment (T1), while walking with the EMAG Active SC-KAFO and one month (T2) and three months after supplying the new NEUROTRONIC SC-KAFO (T3).

Intervention

A custom-made stance control knee-ankle-foot orthosis (SC-KAFO) with the NEUROTRONIC system knee-joint build in

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Eligibility criteria

Inclusion criteria

- using an E-MAG Active SC-KAFO at least when walking outside and that is not defective;

- age between 18 and 80 years;

- < 10 degrees knee valgus deformity;

- < 10 degrees knee flexion contracture;

- able to walk for 6 minutes continuously, with or without assistive devices.

Exclusion criteria

- no indication for a SC-KAFO upon examination (e.g. due to sufficient quadriceps strength)

- circumduction in swing phase of the affected leg during gait;

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50174
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6892
NTR-old	NTR7079
CCMO	NL63902.018.17
OMON	NL-OMON50174

Study results