Gait and user experiences of the NEURO TRONIC stance-control knee-ankle-foot orthosis (SC-KAFO): a comparative evaluation to the E-MAG Active SC-KAFO.

Published: 11-01-2018
Last updated: 15-05-2024

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 to demonstrate superiority of the NEURO TRONIC SC-KAFO on walking energy cost,...

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

Summary

ID

NL-OMON50174

Source
ToetsingOnline

Brief title
Gait and user experiences with the NEURO TRONIC SC-KAFO.

Condition

- Neuromuscular disorders

Synonym
flaccid paresis; muscle disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Fior & Gentz,Fior & Gentz en OIM orthopedie,OIM orthopedie

Intervention

Keyword: Muscle weakness, Stance-control knee-ankle-foot orthosis, Treatment outcome, Walking ability

Outcome measures

Primary outcome

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 outcome

Secondary endpoints include spatiotemporal parameters and joint angles and net joint moments during gait (measured by a 3D gait analysis), and user experiences with the SC-KAFO (measured with a questionnaire).

Study description

Background summary

People who have knee instability that is associated with weakness of the knee extensor muscles 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 and the NEURO TRONIC knee-joint. 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.

Study objective

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 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

The design for this study includes a prospective intervention study with three repeated measurements, i.e. at baseline, walking with the current E-MAG Active SC-KAFO (T0); and after 1 month (T1) and 3 months (T2) of walking with the NEURO TRONIC SC-KAFO. The total duration of the study will be minimum 19 weeks.

Intervention

The intervention includes a custom-made stance control knee-ankle-foot orthosis (SC-KAFO) with the NEURO TRONIC system knee-joint build in. NEURO TRONIC SC-KAFOs will be prescribed and fabricated by one orthotic company (OIM orthopedie, location Noordwijkerhout, The Netherlands).

Study burden and risks

Patients will be asked to visit the AMC minimum 7 times for prescription of the NEURO TRONIC SC-KAFO and to participate in the measurements (intake (10 minutes), physical examination (20 min), muscle strength assessment (30 min), C-Mill test (25 min), 6-minute walk test (30 min) and 3D gait analysis (1.5 hours). Baseline measurement visits will be scheduled simultaneously with the consultancies for SC-KAFO treatment (casting, fitting and delivery), to limit the number of visits to the medical centre. In addition to the tests, patients will be asked to fill in a questionnaire. The total duration of completing this questionnaire is estimated at 20 minutes. Baseline as well as follow-up measurements are non-invasive.

Possible risks related to the intervention (NEURO TRONIC SC-KAFO) are considered minimal. The investigational product is CE certified, already used in clinical practice for several years, and the orthotist fabricating the NEURO TRONIC SC-KAFOs is very well experienced. Therefore the occurrence of medical events is considered minimal.

Practical relevance of the study is that our evaluation of the efficacy of

stance control securing of the NEURO TRONIC knee-joint versus the E-MAG Active knee-joint contributes to improving orthotic management in patients with lower limb muscle weakness in the (near) future.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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).

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):	14-03-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	stance-control knee-ankle-foot orthosis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-01-2019
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

ID: 20209
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63902.018.17
OMON	NL-OMON20209