Multinational randomized controlled cross-over trial comparing C-brace to conventional knee ankle foot orthoses with respect to balance, fall risk and activities of daily living in patients with lower limb impairment..

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The aim of this study is to investigate 1. the extent to which patients who have paresis/non-spastic paralysis of the lower extremity and who are moderately active experience an improvement in the (trunk) balance through the use of a computer-...

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

Summary

ID

NL-OMON48301

Source
ToetsingOnline

Brief title
Functional added value of new microprocessor-controlled orthosis

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
damage to the spinal cord, incomplete spinal cord injury

Health condition

post-polio syndroom, trauma, neurologische aandoeningen zoals multiple sclerose en polyneuropathieen

Research involving
Human

Sponsors and support

Primary sponsor: Otto Bock BV
Source(s) of monetary or material Support: industrie

Intervention

Keyword: balance, falls, orthosis, pareses lower limb

Outcome measures

Primary outcome

Berg Balance Scale. This is a validated and widely used 14-item scale developed

to measure balance in adults.

Secondary outcome

Clinical tests:

Dynamic Gait Index (DGI)

Stair Assessment Index (SAI)

6-minute walk test

Questionnaires:

Activity-specific balance confidence (ABC) Scale

EQ-5D-5L

Medical Outcomes Study Short Form (SF-36)

Orthotics & Prosthetics User Survey (OPUS)

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)

Reintegration to Normal Living (RNL) Index questionnaire

Work limitations questionnaires WLQ-25

Study description

Background summary

Some patients with paresis/paralysis of the lower extremity due to incomplete paraplegia, polio/ post-polio syndrome, MS, CVA, CIAP/CIDP, HMSN II, arthritis or trauma require a *Knee Ankle Foot Orthosis* (hereafter given by its Dutch acronym *KEVO*) or, in layman*s terms, a *long leg brace*. The problem with this is that the conventional KEVO *locks* the affected leg during extension while walking, which leads to an abnormal gait. Amongst other things, this causes increased energy consumption, pain and reduced mobility. The development of aids such as orthoses and prostheses has made great progress and in recent decades, computer-controlled knees have been developed for patients with leg amputations. More recently this technology has also been used in knee-ankle orthoses (KEVOs).

Research on these advances has so far been limited to subjective questionnaires. Ideally, the research would consist of a combination of objective measurements and subjective questionnaires, in order to assess improvements in the disorder as well as activities and participation levels (ICF model) (1). *Disorder* means the pathology of the physiological and mental properties of the human organism as well as the anatomical properties that relate to the presence, position and continuity of parts of the human body, such as a reduction of balance and muscle strength. Activities are the parts of a person*s actions, such as self-care, standing and walking. Participation means a person's participation in social life, such as work and hobbies.

Reference:
1. World Health Organisation. International Classification of Functioning, Disability and Health: ICF; 2001.

Study objective

The aim of this study is to investigate
1. the extent to which patients who have paresis/non-spastic paralysis of the lower extremity and who are moderately active experience an improvement in the (trunk) balance through the use of a computer-controlled KEVO compared to the

conventional KEVO.
2. whether the use of a computer-controlled KEVO in patients with paresis/non-spastic paralysis of the lower extremity and who are moderately active leads to a decrease in the number of fall incidents, an increase in the independence of activities of daily life and improved quality of life compared to a conventional KEVO?

Study design

Prospective international multicentre randomised crossover study

Intervention

A computer-controlled knee-ankle-foot orthosis called a C-Brace, knee-ankle-foot orthosis, dynamic long leg brace.

Study burden and risks

The loads experienced by test subjects participating in this study consist of a) 10 hours of training by a specialised physiotherapist, spread over 2 weeks, b) 1-2 hours training by physiotherapist when patients go back to their own KEVO, c) fitting of experimental orthosis by orthotist 2 hours and d) 8.5 hours of testing spread over 5 moments over a 43-week period. The patient will wear the C-brace for a period of 3 months.

Patients suffering loss of strength in a leg and who are mobile with a knee-ankle-foot orthosis run a low risk of falling. This can be done with either their own orthosis or with the test orthosis. The risk of falling is minimised because:
1) The patients participating in the study have had rehabilitation treatment in the past that was aimed at, amongst other things. safe functioning with a KEVO.
2) They receive a maximum of 10 hours of training during the study to ensure that they function safely with the trial orthosis. When the patient goes back to their own KEVO, evaluation and training will be given if necessary. The orthopaedic instrument maker and the physiotherapist involved are experienced in treating patients with paresis/paralysis of the lower extremity.
3) The test orthosis will be made in a workshop that has been specifically approved for the standardised and high-quality manufacture of this orthosis.
4) A risk analysis has been carried out by the manufacturer (see Investigators Brochure, Section 8). This showed that the risk was acceptable or as low as reasonably achievable after implementing adequate measures.

The performance of the study is justified to my opinion taking in consideration the load and/or risks for the patients involved in the study because the added-value of the KAFO will lead to a significant improvement in the level of functioning of the participant and patients with impaired functioning of the

lower extremity. The expected added-value will be in accordance with literature.

SUPPLEMENTARY from 1 July 2020:
To minimize the potential infection risk, patients are requested to wear face masks/face shields and keep one-and-a-halve metre distance (social distancing) to other people. If the patient has a high risk profile, the guidelines from the RIVM are followed. Om het risico op infectie met COVID-19 te minimaliseren, wordt aan de proefpersoon gevraagd een mondkapje te dragen en anderhalve meter afstand te houden tot anderen. Mocht de proefpersoon tot de risicogroepen behoren, dan worden in Hoensbroek de richtlijnen van het RIVM gevolgd om het risico van infectie zo klein mogelijk te houden door de volgende maatregelen:
During patient visits, every effort will be taken to minimize a potential infection risk by:
• limiting the number of staff to a minimum,
• providing sufficient protection material to the patients as well as to the staff as adviced by RIVM.
• minimizing the length of stay necessary for the patients and
• maximizing the distance between patients and staff as much as possible.

In case of increasing health risk or for any other reason, all enrolled subjects may withdraw from the study at any time.

Therefore, it can be concluded that, given that all mitigation measures described above are taken, the risks associated with a study visit during the COVID-19 pandemic are acceptable when weighed against the benefits that this research can generate for the individual and the population in general.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patiënt with an unilateral paresis/paralysis of the lower extremity
• Patient is >= 18 years old
• Prior active and compliant use of unilateral or bilateral KAFO or SCO in the past 3 months prior to enrollment in the study
• Patient has been tested with the Trial Tool (DTO) and demonstrated the potential to utilize the C-Brace successfully
• Patient has a BBS score < 45
• Patient meets minimum physical requirements to be fitted with a C-Brace, such as muscle status, joint mobility, leg axis and proper control of the orthosis must be guaranteed.
• The User must fulfill the physical and mental requirements for perceiving optical/acoustic signals and/or mechanical vibrations
• The existing muscle strength of the hip extensors and flexors must permit the controlled swing-through of the limb (compensation using the hip is possible).
• Patient*s commitment to use C-Brace 2 at least 1-2 hours per day 5 days per week-
• Patient is willing and able to independently provide informed consent.
• Person is willing to comply with study procedures

Exclusion criteria

• Patient who is not using an orthosis at least 1 to 2 hours/ day for 5 days per week
• Patient with body weight > 125 kg (includes body weight and heaviest object (weight) carried)
• Patient with flexion contracture in the knee and/or hip joint in excess of 10°
• Patient with uncontrolled moderate to severe spasticity (relative

contraindication moderate spasticity)
• Leg length discrepancy in excess of 15 mm
Patient with unstable neurological or cardiovascular/pulmonary disease, cancer
• Patient is < 18 years old
• Pregnancy
• Patient using a C-Brace
• Patient with known vertigo or with history of falls unrelated to orthosis use or unrelated to motor disability
• Patient is not able to answer the self-administered questionnaires independently; for patients with upper extremity impairment is it allowed to verbally answer the questions.
• Patient participating already in a study during this study*s duration

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2019
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	C-brace knee ankle foot orthosis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-09-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
Other	Het onderzoek is geregistreerd in clinicaltrials.gov NCT03906656. (https://www.clinicaltrials.gov/ct2/show/NCT03906656?term=C-Brace&rank=2)
CCMO	NL70137.015.19