Effect of different types of ankle foot orthoses on weight-bearing and static and dynamic balance contribution of the paretic and non-paretic leg in stroke patients.

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- What are the effects of different types of ankle foot orthoses on weight-bearing and static and dynamic balance contribution of the paretic and non-paretic leg in stroke patients? - What are the effects of different types of ankle foot orthoses on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON30575

Source
ToetsingOnline

Brief title
Effect of ankle foot orthoses on balance contribution in stroke patients

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: ZON-MW

Intervention

Keyword: Ankle Foot Orthosis (AFO), balance, stroke, weight-bearing

Outcome measures

Primary outcome

Main study parameters are

1) static balance contribution of the paretic and non-paretic leg;

2) dynamic balance contribution of the paretic and non-paretic leg;

3) functional (balance) tests.

Secondary outcome

not applicable

Study description

Background summary

An impaired balance control is a major problem in stroke patients. Ankle Foot Orthoses (AFO) are generally prescribed to provide stability, even though the literature is inconclusive about the effects of AFOs. In rehabilitation improvement of weight-bearing symmetry is traditionally an important goal to improve motor functioning and ADL independence. However, in earlier research was found that the contribution of the paretic leg to balance was smaller than the contribution of the paretic leg to weight-bearing. This led to the conclusion that the contribution of the paretic leg to balance is not a reflection of the weight distribution. This conclusion was based on measurements while some patients wore an AFO, which may have influenced postural balance and thus the results of the study. To further investigate the effects of AFOs on balance performance in stroke patients a new research will be conducted. In this research the effects of different types of AFOs on weight-bearing and balance contribution of the paretic and non-paretic leg and

the effects on functional (balance) tests will be studied.

Study objective

- What are the effects of different types of ankle foot orthoses on weight-bearing and static and dynamic balance contribution of the paretic and non-paretic leg in stroke patients?
- What are the effects of different types of ankle foot orthoses on functional (balance) tests?

Study design

A cross-over design with randomisation for standing with and without wearing their own AFO on the affected leg will be used. Three groups of subjects with different types of AFOs will be measured.

Intervention

Stroke patients with three different types of AFO will be included in this study. All subjects will perform static and dynamic balance measurements on a movable force platform, both with and without wearing their AFO, while wearing their own shoes. Dynamic balance measurements consist of random, multisine movements of the force platform in the forward-backward direction (1 dimension) of maximal 5 cm. Subjects will also perform functional (balance) tests with and without wearing their AFO. To further categorise the three subject groups ankle stiffness, ankle spasticity, selective muscle control and trunk movements will be measured.

Study burden and risks

During the study subjects will be measured two times. The first time will be in the VR lab to measure weight-bearing and static and dynamic balance contribution of the paretic and non-paretic leg. The second time will be in the gait lab for functional (balance) tests. Subjects might lose their equilibrium during the measurements. Therefore a safety harness suspended from the ceiling will be used when subjects stand on the force platform in the VR lab to prevent falling. During all the measurements an experienced physiotherapist will accompany the subjects.

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

- single and first ever unilateral ischaemic or haemorrhagic hemiparetic stroke
- age 18 years or older
- wearing an AFO daily for at least six months of one of the three included types
- able to maintain independent unsupported stance with shoes on, with and without wearing an AFO on the affected side, for at least 90 seconds
- able to walk for 10 m with or without assisted device
- able to follow simple verbal command or instructions

Exclusion criteria

- medication or non-stroke related disorders that could affect balance
- suffering from comprehensive aphasia
- suffering from neglect

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	20-03-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
CCMO	NL16299.080.07