

Effects of high orthopedic shoes on walking ability in stroke patients.

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The aim of this study is to determine the effect of high orthopedic shoes on walking ability in stroke patients and to evaluate the effect of a period of exercising with high orthopedic shoes. Primary question: To evaluate quantitative and qualitative...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33727

Source

ToetsingOnline

Brief title

Effects of high orthopedic shoes

Condition

- Central nervous system vascular disorders

Synonym

cerebrovascular attack, fit

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: stichting KFA

Intervention

Keyword: orthopedic shoes, stroke, walking ability

Outcome measures

Primary outcome

Walking ability is operationalised by the Timed up and go test (TUG), the 2 minutes walking test and by comfortable walking speed measured by gait analysis.

Secondary outcome

Gait parameters are measured using gait analysis. Subjective impressions are measured by a questionnaire.

Study description

Background summary

One of the major goals during rehabilitation of stroke patients is regaining the ability to walk. Gait abnormality after stroke is due to a variety of disorders, depending on the localization and severity of the lesion. In stroke patients motor tasks are not performed automatically and cognitive control is needed during walking. Studies show that performing a verbal task during walking in patients with brain damage has a negative effect on walking ability. By compensating paresis and coordination disorders and by correcting joint immobility and instability, walking ability may be advanced. For this purpose a variety in leg orthoses can be prescribed. Insight into the effect of orthoses on the walking ability and gait of stroke patients is important while making a decision on what sort of orthosis to prescribe. Ankle foot orthoses can have a positive effect on walking ability and gait characteristics of stroke patients. Research on the effect of high orthopedic shoes on walking ability in stroke patients is virtually lacking.

Study objective

The aim of this study is to determine the effect of high orthopedic shoes on walking ability in stroke patients and to evaluate the effect of a period of exercising with high orthopedic shoes.

Primary question:

To evaluate quantitative and qualitative effect of high orthopedic shoes on walking ability in stroke patients as well as on dual task interference.

Secondary questions:

To evaluate the effect of a period of exercising with high orthopedic shoes on quantitative and qualitative parameters as well as on dual task interference.

Study design

The design is longitudinal prospective study.

Study burden and risks

The measurements are performed twice: no longer than two weeks after the patient has worn the high orthopedic shoes for the first time (T1) and after the patient has worn the high orthopedic shoes for a period of 2 months, plus or minus 2 weeks (T2).

The measurements include a short clinical examination (to evaluate spasticity, mobility and voluntary movements), a Timed up and go test and 2 Minute walking test in which the patient is asked to rise from a chair and walk short distances and a video registration of the patient walking a short distance (gait analysis). At the end the patient is given a questionnaire of 13 multiple choice questions.

The clinical examination, Timed up and go test, 2 Minute walking test and gait analysis are widely used by rehabilitation specialists and physical therapists during the rehabilitation period. These tests are associated with minimal physical burden and risks for patients.

One measurement takes approximately 3 hours, in between the tests the patient is able to rest on a chair. During the walking tests a person is walking beside the patient to ensure safety.

With this study we can obtain useful scientific data, which give important clinical information. Participation is associated with minimal risk and physical burden. Therefore, in my opinion, this study is justified.

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

Ischemic or hemorrhagic stroke

Spastic hemiparesis of the lower extremity

Older than 18 years

Wearing high orthopedic shoes to improve walking ability, since no longer than two weeks

Able to understand Dutch

Sufficient physical condition to perform tests

Exclusion criteria

Other neurological, orthopedic or vascular conditions that have an effect on walking ability

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-08-2009
Enrollment: 25
Type: Actual

Ethics review

Approved WMO
Date: 23-07-2009
Application type: First submission
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL23388.078.09