The effect of of a spinal orthosis on gait and balance in patients with symptomatic osteoporotic vertebral compression fractures (OVCFs)

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

Summary

ID

NL-OMON43909

Source
ToetsingOnline

Brief title
Gait and balance in patients with OVCF

Condition

- Fractures

Synonym
Osteoporotic vertebral compression fracture, vertebral fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Balance, Gait, Orthosis, OVCF

Outcome measures

Primary outcome

Primary Objective:

1. To assess the effect of the Osteoline® plus orthosis on postural balance

(margins of stability) in patients with OVCF.

Secondary outcome

Secondary Objectives:

1. To assess the effect of the Osteoline® plus orthosis on gait parameters;

2. To assess the effect of the Osteoline® plus orthosis on quality of life

(VAS, Tinetti scale, Qualeffo-41);

3. To assess the effect of the Osteoline® plus orthosis on sagittal alignment

as determined on plain radiographs;

4. To assess the effect of the Osteoline® plus orthosis on trunk motion.

Study description

Background summary

Vertebral fractures are the most common clinical manifestations of osteoporosis. Osteoporotic compression vertebral fractures (OVCFs) can result in hyperkyphosis; and both are associated with diminished daily functioning and an increased risk of falling. Spinal orthosis are known to reduce pain and increase quality of life in patients suffering from OVCFs. The purpose of this study is to examine whether the use of spinal orthosis also increases the margins of stability during walking in this patient group and thereby decreases

the risk of falling.

Study objective

The data will be used in order to evaluate statistical variability (mean, SD) in an attempt to predict an appropriate sample size prior to the RCT based on the effect size, alpha and beta.
The aim of the RCT is to assess the effects of the Osteoline® plus orthosis on pain, balance (margins of stability) and gait parameters in patients with OVCF.

Study design

Prospective, single center, baseline-controlled pilot study.

Intervention

All subjects are prescribed to wear the thoracolumbar orthosis Osteolind® plus in the acute stage for the entire day (during the night is optional). In the subacute stage the subjects will be requested to wear the Osteolind® plus orthosis at least 6 hours daily, and after three months for at least 3 hours daily until the final follow-up at six months.

Study burden and risks

The risk of the gait analysis is negligible. A safety harness provides protection against falling. It will avoid subject falling on or off the treadmill while performing training. The safety harness is secured with a life line to the ceiling. The gait analysis (questionnaire included) compromises the only burden; all other interventions are equal to normal clinical practice. The gait analysis will take approximately 60 to 90 minutes.

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

* Female;
* Age 55 years or older;
* Fully ambulatory subject (ability to perform a 15 meter walk test without walking aids);
* Symptomatic osteoporotic vertebral compression fracture;
* Presenting at emergency department MUMC;
* Willing and able to provide informed consent.

Exclusion criteria

* Male;
* Unstable vertebral fractures;
* Fractures due to high energetic trauma;
* Neurologic deficit, active cancer;
* Alcohol or drugs use affecting balance or influencing central nervous system (within 48 hours before testing);
* Psychiatric or mental disease;
* Insufficient cognitive or language skills to complete questionnaires.

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):	13-10-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Osteolind® plus orthosis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 28889
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL52978.068.15
Other	Volgt nog
OMON	NL-OMON28889