Gait and balance in patients with an osteoporotic vertebral compression fracture: The effect of bracing.

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	-

Summary

ID

NL-OMON28889

Source
Nationaal Trial Register

Brief title
Gait and balance in patients with OVCF

Health condition

Osteoporotic vertebral compression fractures

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The main study parameter is the assessment of margins of stability (MOS) at baseline, at six weeks and at six months follow-up.
The patients will walk in a Computer Assisted Rehabilitation ENvironment (CAREN). The

effects of walking with and without orthosis will be assessed on ‘Margins Of Stability’ (MOS). The MOS is defined as the distance between a velocity adjusted or ‘extrapolated’ position of the center of mass (XcoM) and the edge of an individiual’s base of support (BOS) at any given instant in time. The MOS is directly related to the impulse (I) required that causes instability. Center of mass (COM) position will be estimated as the average position of the four pelvis markers (right and left anterior and superior iliac spine).

Secondary outcome

1. To assess the effect of the Osteolind® plus orthosis on gait parameters, such as walking velocity, cadence, step time, and step length;

2. To assess the effect of the Osteolind® plus orthosis on quality of life (VAS, Tinetti scale, Qualeffo-41);

3. To assess the effect of the Osteolind® plus orthosis on sagittal alignment as determined on plain radiographs;

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

5. To assess the effect of the Osteolind® plus orthosis on the incidence of falls.

Study description

Study objective

Pilot study

Study design

1 week, 6 weeks and 6 months after visit at ER

Intervention

All subjects are prescribed to wear the thoracolumbar orthosis Osteolind® plus (Werkmeister, Wanfried, Germany) in the acute stage (the first six weeks after presentation at the Emergency department) for the entire day (during the night is optional). In the subacute stage (week six of disease onset) 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.

Contacts

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Eligibility criteria

Inclusion criteria

-Female;

-Age 60 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 requiring surgery;

-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);

-History of neurogenic or myopathic disorders impairing sensory or motor functions;

-Psychiatric or mental disease;

-Insufficient cognitive or language skills to complete questionnaires.

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-07-2015
Enrollment:	15
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43909
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5111
NTR-old	NTR5243
CCMO	NL52978.068.15
OMON	NL-OMON43909

Study results