Functional outcome one year after osteoporotic vertebral compression fractures

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Primary objective:1. To assess functional outcome of patients with an osteoporotic vertebral compression fractures after one year of follow-up.Secondary objectives:1. To assess radiological deterioration of sagittal alignment during one year of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON42227

Source
ToetsingOnline

Brief title
FORCE

Condition

- Fractures
- Nervous system, skull and spine therapeutic procedures

Synonym
osteoporosis, vertebral fracture

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: SafeOrthopaedics

Intervention

Keyword: osteoporosis, quality of life, sagittal balance, vertebral compression fractures

Outcome measures

Primary outcome

The main study endpoint is the functional outcome one year after an OVCF,

measured by pain level and quality of life.

Secondary outcome

Sagittale balance, measured on X-rays of total spine

Mineral bone density will be measured by DXA (mg per cm2, T-score) and finite

element analysis of quantitative CT scans will be conducted to measure

volumetric BMD (mg per m3).

Quality of life after three and six months

Physical activity, Accelerometer-based measurements of movement

Study description

Background summary

Osteoporosis is one of the ten most common diseases worldwide. In 2007, more than 142.000 people in the Netherlands were diagnosed with osteoporosis. Moreover, based on demographic data as population growth and increase in ageing, an increase of 38% is estimated in 2025. The most common sequelae of osteoporosis are vertebral compression fractures with approximately half of all osteoporotic fractures annually in the USA. Even more, the actual incidence of vertebral fractures is said to be highly underestimated given the large number of fractures of the vertebrae that is never clinically diagnosed. The World

Health Organisation (WHO) defines osteoporosis as a T-score (standard deviation [SD] score related to mean bone mineral density (BMD) of young [20-29 years] normal Caucasian women) equal to, or below, -2.5. BMD is measured by dual X-ray absorptiometry (DXA), which is the current gold standard for diagnosing osteoporosis because of its low cost, low radiation and ease of use. However, limitations of DXA in assessing bone strength and the corresponding fracture risk are more and more recognised. The accuracy to predict fracture risk is said to increase with site-specific measurements. Volumetric BMD (vBMD) can be measured non-invasively by quantitative computed tomography (QCT). Finite element analysis estimates vertebral strength for a simulated compression over-load. To evaluate 3D bone geometry, QCT has been found to be more sensitive than DXA. Vertebral fractures are strongly correlated with increasing age, which is associated with decreasing bone density. Francis et al. stated that the risk of developing a vertebral fracture is increasing more than two times for every standard deviation below average vertebral BMD. Besides age, other factors as genetic predisposition and lifestyle choices like smoking and excessive alcohol intake increase the risk of osteoporosis. Furthermore, the risk of developing an adjacent vertebral fracture within a year of an initial vertebral fracture in osteoporotic patients is 20%.

Numerous studies have been published about the optimal treatment of a osteoporotic vertebral compression fracture. In the scientific literature, a controversial discussion is ongoing whether to treat conservatively or surgically and when a surgical intervention is indicated, which procedure should be performed. Conservative treatment, consisting of painkillers such as NSAIDs (non-steroidal anti-inflammatory drugs) and relatively immobilization with physical therapy, can help relieve the pain during the healing process. Also, bracing is commonly used for symptomatic management. There is, however, little evidence on its application for osteoporotic compression fractures. Ability to perform activities in daily living (ADL) and quality in life may increase in some cases, but patient discomfort such as skin breakdown and respiratory volume restriction is reported frequently too. As such, many authors have moved away from recommending rigid braces. Prescription of anti-resorptive osteoporosis medications can increase BMD and therefore reduce the risk of a additional fracture. Although, low success rates are found by Maeda et al. by non-compliance due to adverse side effects, such as nausea. As well as conservative treatment, surgical intervention is mostly aimed at pain relief but is intended to improve functional outcome too. In some cases an absolute indication for surgical intervention is recognised. These include compression of the spinal cord or cauda equine which results in loss of sensation and/or weakness in the lower extremities. In these cases an emergency surgery may constitute. In other cases, when an initial conservative therapy does not adequately relieve the pain, surgical intervention should be considered. Approximately one-third of osteoporotic vertebral compression fractures does not heal with conservative treatment. The loss of height resulting from the fracture may result in a resultant kyphotic deformity or decreased lumbar lordosis, which can be progressive in cases of delayed or non-union. This collapse may shift the plumb line of C7 ventrally. Sagittal

imbalance occurs as this plumb line passes in front of the femoral heads. Even after the fracture is healed, this may lead to chronic back pain and associated fatigue due to actively increasing lumbar lordosis as initial compensation. If additional extension of the lumbar spine is not possible, tilting the pelvis backwards adds further compensation. Flexing the knee joints is the last step in compensating an imbalance situation of the spine. This compensation mechanism can be seen on full spine X-rays (C1 to pelvis including the hips and femur heads) and measured by standard pelvic parameters such as pelvic incidence (PI), pelvic tilt (PT) and sacral slope (SS). This method is called *full balance integrated* (FBI) and is widely studied by le Huec et al. to assess the balance of the spine. Sagittal imbalance can limit a patient*s quality of life and ADL severely. Another important issue of quality of life is physical activity. With the aging process, besides a decrease in bone density, skeletal muscle mass and strength is decreased as well. (Doherty, 2003) For conservation of musculoskeletal health, physical activity is recommended as an effective intervention. (Maltais, 2009) Accelerometer-based measurement of movement is an accepted method for monitoring physical activity (Mathie, 2004). Association of loading of physical activity and bone and muscle strength is studied by Chahal with accelerometric methods (2014). However, little is known about the association with quality of life.
Fracture patterns in osteoporotic compression fractures have been studied by Genant et al. This method assesses the severity of vertebral fractures by visual determination of the extent of vertebral height reduction and morphological change, and vertebral fractures are differentiated from other, non-fracture deformities. This makes the classification suitable for clinical application.
Aim of this observational cohort-study is to evaluate the functional outcome of patients with an osteoporotic vertebral compression fracture and its correlation with deterioration of sagittal alignment, severity of osteoporosis and type of fracture and rate of delayed or non-union. Our hypothesis is that poorer functional outcome and delayed or non-union correlates with poor sagittal alignment at inclusion, severe osteoporosis and high Genant classification (Grade 2-3).

Study objective

Primary objective:
1. To assess functional outcome of patients with an osteoporotic vertebral compression fractures after one year of follow-up.
Secondary objectives:
1. To assess radiological deterioration of sagittal alignment during one year of follow-up
2. To assess the effect of osteoporosis on deteriorated sagittal alignment
3. To assess the effect of the type of fracture on deteriorated sagittal alignment
4. To assess the rate of non-union in relation to osteoporosis and type of fracture

5. To assess the effect of physical activity on quality of life in patients with an osteoporotic vertebral compression fracture.

Study design

A prospective, single centre, observational study. Patients will be monitored during a period of one year. Follow-up will take place at one week, three, six and 12 months after inclusion.

Study burden and risks

Participation in this study doesn't influence the regular treatment. However, there will be extra radiation because of extra diagnostic test, such as a CT-scan at inclusion, full spine X-rays instead of X-rays of the thoracic resp. lumbar spine. A bone scintigraphy will be done at 3 months for all subjects. Subjects will be wearing an Accelerometer to measure their physical activity twice for one week. Subjects receive this meter at their visit in the hospital and can return it by mail.

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

male and female patients aged 50 years or older, fracture of the thoracal resp lumbal spine, fracture less than one week old, low-energy trauma, signed informed consent

Exclusion criteria

neurologic deficit, active cancer, psychiatric or mental disease, insufficient cognitive or language skills to complete questionnaires

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	110
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-08-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-03-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL50569.100.15