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Evaluation of safety and effectiveness of the Osseofix Spinal Fracture Reduction System in treating spinal compression fractures

Submission date
11/10/2011

Recruitment status
No longer recruiting

Registration date
24/01/2012

Overall study status
Completed

Last Edited
30/04/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and aims
Clinical vertebral fractures affect an estimated 1.4 million people worldwide every year. It has been estimated that medical costs due to spine fracture in the United States exceeded $1 billion in 2005, an amount predicted to surpass $1.6 billion by 2025. Current treatments for vertebral fractures include non-surgical and surgical treatment. Despite non-surgical management, including analgesia (pain relief), bed rest, physiotherapy, and back bracing, pain sometimes resolves slowly and can persist. Patients with vertebral fractures have physical deformities that affect functional and mobility outcomes as well as psychosocial outcomes. Furthermore, vertebral fractures lead to a reduced quality of life as well as increased back pain. The Osseofix spinal fracture reduction system facilitates the treatment of spinal fractures by providing internal fixation and stabilization using a titanium implant (Osseofix) with polymethylmethacrylate (PMMA) bone cement. The unique design represents a simple procedure which allows for more surgeon control, prevents from vertebral re-collapse and reduces the risk of balloon related complications. Despite the advantages in recent studies, there is no published clinical data about the Osseofix spinal fracture reduction system. The need to clinically evaluate the safety and effectiveness led to the present study. We will follow up a number of maximum 150 patients with confirmed VCFs who have been treated with the Osseofix system. Quality of life, function, disability, pain as well as vertebral height restoration, volume of cement used and complications related to the procedure or the implant will be evaluated. The patients will be assessed before the operation and at baseline (after the operation) and at 1 month, 3 months, 6 months and 1 year after the procedure. Upon completion of the study, statistical analysis will be performed and the results at the end of the study will be presented and published.

Who can participate?
Patients aged 21 or older with at least one (1-3) acute thoracic or lumbar vertebral fracture between T6-L5 which is suitable for treatment with internal fixation and stabilization.

What does the study involve?
Before surgery participants undergo routine investigations including blood tests, x-rays, an MRI

scan, and if needed a CT scan. A DEXA scan for the measurement of bone density may be undertaken if a participant is likely to have osteoporosis (thinning of the bones). Participants are also asked to complete some questionnaires which are routinely used for the evaluation of pain, quality of life, function and disability. The surgical procedure takes place at the Queens Medical Centre under the care of a spinal surgeon experienced in the use of the Osseofix system. After the surgery participants return to the recovery ward and receive the usual care. Before discharge participants have to have x-rays and also complete the same questionnaires you received before the operation. The overall study follow up is 1 year. During that time participants have to attend the spinal outpatient clinics and have x-rays of the fracture site after 4 weeks, 3 months, 6 months and 1 year.

What are the possible benefits and risks of participating?
Following fracture reduction and vertebral augmentation with the Osseofix implant you will get immediate pain relief and you will mobilise better and much earlier. In addition the initial spinal deformity caused by the vertebral fracture will be corrected to a significant degree, allowing for better body posture and assist with mobility. The application of the Osseofix implant represents a minimally invasive procedure, which means that it causes very little trauma to the surrounding tissues, less complications in terms of bleeding or pain, and it can be performed under local anesthesia alone if the other anesthetic options are contraindicated. The most common risks which have been reported with procedures similar to Osseofix (balloon kyphoplasty) are cement leak (7-11%) and formation of a new fracture (18%). Less common problems which have been reported rarely during or after balloon kyphoplasties were: balloon burst, bleeding around the spine and nerve injury with loss of leg use. The Osseofix system does not advocate the use of a balloon, avoiding the risk of balloon-related complications. Although studies have shown promising results, the lack of published clinical data about the Osseofix may cause some scepticism about the safety and effectiveness of the procedure but this is the purpose of the present study.

Where is the study run from?
Centre for Spinal Studies and Surgery, Queens Medical Centre (QMC) Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2011 to November 2013

Who is funding the study?
Alphatec Spine, the manufacturer of Osseofix (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11SP002

Study information

Scientific Title
Evaluation of safety and effectiveness of the Osseofix Spinal Fracture Reduction System in treating spinal compression fractures

Study objectives
The aim of the study is to assess clinically, the safety and effectiveness of a new innovative implant called (Osseofix) for the treatment of osteoporotic vertebral compression fractures (VCFs). The Osseofix spinal fracture reduction system provides internal fixation and stabilization using a permanent implant made of titanium metal and bone cement. It is applied in a very similar way with the most common procedure used for the treatment of VCFs which is called balloon kyphoplasty. The main difference between the two systems is that the Osseofix use a permanent, expandable titanium metal mesh instead of an inflatable balloon for the restoration of the fracture. Furthermore the Osseofix has demonstrated in recent biomechanical studies the advantage of improved vertebral height maintenance and the use of a smaller volume of bone cement for the restoration of the fractured vertebra. The above characteristics have as a result a reduced risk of cement but also balloon related complications.

The hypothesis of this study is that the Osseofix system is more effective and safe from the balloon kyphoplasty, which represents the standard invasive treatment for the treatment of VCFs.

The objectives of the study is to assess:
1. The pain levels
2. The quality of life
3. The function /disability
4. The complications /adverse effects
5. The amount of radiological correction in a number of patients suffering with acute VCFs who have been treated with the Osseofix system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reseach Ethics Committee Committee East Midlands, 03/11/2011, ref: 11/EM/0397

Study design
Single cohort study using consecutive prospectively collected data

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute vertebral compression fractures between levels T6 and L5

Interventions
1. Enrolment in the study and signing of an informed consent, pre-operative assessment including clinical and radiological evaluation
2. Surgery involving fixation of the vertebral fractures
3. Post-operative evaluation (clinical and radiological assessment)
4. First follow up, 4 weeks post operatively for clinical evaluation and radiological assessment.
5. Second follow up, 3 months post operatively for radiological and clinical evaluation
6. Third follow up, 6 months post operatively for clinical evaluation only
7. Last follow up, 12 months post operatively for radiological and clinical evaluation

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Quality of life measures:
1.1. SF-36 Subscale score physical component summary PCS6
1.2. EuroQol 5 Dimention Questionnaire
2. Pain measures
2.1. Visual Analogue Scale (VAS)
2.2. SF-36 bodily pain
3. Function/Disability measures:
3.1. Oswestry disability Index (ODI)
3.2. Roland Morris disability questionnaire (RMDQ)
4. Complications/adverse events measures - clinical/related to a procedure or a device
5. Radiographic evaluation measures - vertebral height /shape, sagittal balance measurements

Key secondary outcome(s))
1. Number of patients who received additional therapy post operation:
1.1. Physiotherapy
1.2. Walking aids
1.3. Back braces
1.4. Wheelchairs
1.5. Miscellaneous aids
1.6. Other therapy
2. Number of patients who use pain medications pre/ post op
3. Number of patients taking osteoporosis medications throughout the study
4. Fracture measures- fracture type: according to the AO classification Vertebral body involvement based on MRI findings 11 Presence of old vertebral fractures
5. Bone quality - DEXA scan to measure the BMD (assessment of osteoporosis/ osteopenia)

6. Procedure Measures
7. Size of implant used
8. Volume of cement used
9. Intraoperative radiation exposure
10. Duration of surgery

Completion date
01/11/2013

Eligibility

Key inclusion criteria
1. Aged 21 years and above
2. Any male of female patients with vertebral fractures (1-3) caused by osteoporosis, multiple myeloma, or other osteolytic processes
3. Osteoporosis (primary or secondary)
4. Fracture levels between T6-L5
5. Pain VAS ≥4 (1-10)
6. Onset of pain within the last 3 months
7. Recent fractures with bone marrow signal changes on MRI
8. At least 15% decreased vertebral height compared with adjacent vertebrae
9. Progressive height loss or painful pseudoarthrosis
10. VCF morphology suitable for kyphoplasty

(Fracture types A1.1, A1.2, A1.3 and A 3.1 according to the AO classification)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age < 21 years
2. Primary bone tumours
3. Osteoblastic metastases
4. Chronic (old) fractures (> 3 months)
5. Substantial clinical morbidities that preclude the patient from completing the protocol mandated follow-up or which may interfere with the study procedures
6. VCF morphology unsuitable for kyphoplasty (Pedicle fractures ,unstable burst fractures, spinal injuries in which the pedicles are dissociated from the vertebral body or spinal fractures in which posterior access to the vertebral body is not possible or contra-indicated.)
7. Neurologic deficit
8. Inability to complete follow up (medical, cognitive problems)
9. Prisoners

10. Pregnancy
11. Contraindications for MRI
12. Systemic or local Infection
13. Patients taking uninterruptive anticoagulation therapy

Date of first enrolment
26/01/2012

Date of final enrolment
26/04/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Alphatec Spine (UK)

Funder(s)

Funder type
Industry

Funder Name
Alphatec Spine (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration