Clinical Evaluation of the Crosstrees Pod™ in the Treatment of Pathologic Fracture of the Vertebral Body (Levels T4 - L5) in Adult Patients

Purpose

The clinical trial is being conducted to evaluate the performance of the Crosstrees System in reducing pain and decreasing the risk of cement leakage associated with vertebroplasty and kyphoplasty.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Pathologic Fracture of the Vertebra Due to Osteoporosis</td>
<td>Device: Crosstrees Pod system for PVA</td>
</tr>
</tbody>
</table>

Study Type: Interventional
Study Design:
- Endpoint Classification: Safety/Efficacy Study
- Intervention Model: Single Group Assignment
- Masking: Open Label
- Primary Purpose: Treatment

Official Title: Clinical Evaluation of the Crosstrees® System for PVA in Symptomatic Adult Patients With Acute Vertebral Body Compression Fractures at T4-L5

Resource links provided by NLM:

- MedlinePlus related topics: Fractures, Osteoporosis
- U.S. FDA Resources

Further study details as provided by Crosstrees Medical Inc.:

Primary Outcome Measures:
- Clinically significant improvement in pain as measured using a 10 mm Visual Analog Scale (VAS). In this scale 0 means "no pain" and 10 is "Severe pain". A difference of at least 2 points compared to baseline is regarded as clinically relevant. [ Time Frame: Six months ]
  [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Ambulatory Status/Physical Function [ Time Frame: 24 hours, 2 weeks, 1 month, 3 months, 6 months, 1 year ]
  [ Designated as safety issue: No ]
- Quality of life [ Time Frame: 24 hours, 2 weeks, 1 month, 3 months, 6 months, 1 year ] [ Designated as safety issue: No ]
- Neurological Assessment [ Time Frame: 24 hours, 2 weeks, 1 month, 3 months, 6 months, 1 year ] [ Designated as safety issue: No ]
- Vertebral Body Morphology [ Time Frame: 24 hours, 2 weeks, 1 month, 3 months, 6 months, 1 year ] [ Designated as safety issue: No ]
Enrollment: 135
Study Start Date: June 2009
Study Completion Date: June 2013
Primary Completion Date: June 2013 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Treatment arm</td>
<td>Device: Crosstrees Pod system for PVA</td>
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<tr>
<td>Crosstrees Pod System for PVA.</td>
<td>Minimally invasive spine surgery</td>
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<td>Other Names:</td>
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<tr>
<td>- Vertebroplasty</td>
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<td>- Kyphoplasty</td>
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<tr>
<td>- PVA</td>
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<tr>
<td>- Vertebral Augmentation</td>
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</table>

**Detailed Description:**
Every year in the United States more than 700,000 people suffer from compression fractures of the spinal column, and the number of people affected is much higher across the world. Osteoporosis is the main cause of fractures of the vertebral bodies. Other causes of vertebral fractures include malignant processes including benign lesions (hemangioma) and malignant lesions (metastatic cancers, myeloma), infections and trauma; however, osteoporosis is by far the main cause of this problem.

In a normal person, the vertebral bodies are composed of a porous structure called trabecular or spongy bone encapsulated within a thin external cap of cortical (dense) bone. In a person with osteoporosis, the trabeculae that form the central porous bone become thinner and weaker. When this occurs, the vertebral bodies begin to fracture and become deformed. This deformation of the vertebral bodies is classified into three types, according to the shape: wedge, biconcave, and crush. The degree of severity of these deformations is classified as grade A1.1, grade A1.2, or grade A1.3.

The Crosstrees PVA™ Pod™ is a device designed to percutaneously provide controlled delivery of PMMA bone filler material during vertebral augmentation. The Crosstrees PVA System for Percutaneous Vertebral Augmentation (PVA) is designed for use with Crosstrees Fortibrae PMMA. The system is novel in providing the ability to control the delivery of PMMA to the vertebral body without the need for an additional permanent implant to remain within the patient. The Crosstrees System for Percutaneous Vertebral Augmentation will be used with Crosstrees Access Tools, which are regulated as Class I exempt orthopedic manual surgical instruments.

**Eligibility**

Ages Eligible for Study: 50 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

1. Patient is at least 50 years old.
2. Patient must have a fracture due to diagnosed or presumed underlying primary or secondary osteoporosis (Patients with AO type A1 fractures (all) may be included in the study).
3. Patient must have confirmed acute pain and tenderness over the spine at or near the level of x-ray compression deformity OR positive MRI evaluation.
4. Patient must NOT have more than (3) three vertebral compression fractures located between T4 and L5.
5. Subjects affected vertebral body must have a loss of 0-50% in vertebral height as compared with the height of an adjacent normal vertebral body confirmed by radiological evaluation.
6. Subject fracture is confirmed by MRI imaging including T1, T2 and STIR-weighted studies to determine the type and presence of fracture(s).
7. Subjects affected vertebral body height and geometry is adequate for insertion of access instruments of 5.2mm OD, as determined by the investigator.
8. Subjects pain score is equal to or greater than 5 according to the visual analog scale (VAS).
9. Patient has been evaluated for hematologic disorders or other conditions affecting blood coagulation.
10. Subjects are suitable candidates for standard vertebroplasty or kyphoplasty procedures.
11. Subject is psychosocially, mentally, and physically able to fully comply with this protocol including adhering to scheduled visits, treatment plans, completing forms, and other study procedures.
12. Subject signed the Informed Consent Form prior to any study related procedures indicating that he/she has been informed of all pertinent aspects of the trial.
13. Failure of conservative treatment prior to inclusion: a. failed conservative treatment arm; b. acute therapy treatment arm.
Exclusion Criteria:

1. Patient has significant vertebral collapse, defined as > 50% of the original height of the vertebral body, as measured against the nearest normal vertebral body. Degree of collapse will be determined by using the height of the nearest normal vertebral body to represent 100% and dividing the height of the collapsed vertebral body by the height of the normal vertebral body.
2. Patient has compromised spinal canal.
3. Patient has symptomatic spinal stenosis.
4. Patient has painful VCF with fracture age greater than 6 months.
5. Patient has primary tumors of the bone (e.g., osteosarcoma) or solitary plasmacytoma at site of the index VCF. Patients with these tumors in anatomic sites other than the index VCF are eligible.
6. Patient has a fracture that extends into the posterior vertebral body wall.
7. Patient has neurological compromise (including myelopathy) and instability.
8. Patient has a retropulsion severe enough to cause myelopathy, unless prior surgical decompression is performed.
9. Patient with significant clinical comorbidity that may potentially interfere with long-term data collection or follow-up (e.g., dementia, severe comorbid illness).
10. Patient requires the use of high-dose steroid, IV pain medication, or nerve block to control chronic back pain unrelated to index VCF(s). Patients who receive high-dose steroids for treatment of their cancer (for at least 30 days) are eligible.
11. Patient who may require allogenic bone marrow transplantation during the course of the study.
12. Patient is in need of an open decompression.
13. Patient with burst fracture, and/or pedicle fracture at the treatment level.
14. Patient with a known or suspected allergy to PMMA or allergy to any device material used in the treatment of vertebral fractures. Note that in subjects with allergy to iodine-based contrast, other non-iodine contrast solutions may be used.
15. Patient does not have local pain and tenderness that correlates with MRI evaluation.
16. Patient has a coagulation disorder that cannot be corrected: a. for patients with hematologic disorders or other conditions affecting blood coagulation, a platelet count and internationalized normal ratio (INR), prothrombin time (PT), and partial thromboplastin time (PTT) values should be available at time intervals typical of the treatment center. The Investigator is to evaluate the ranges relative to the normal values of the treatment center laboratory.
17. Patient has an active local or systemic infection.
18. Patient has a previous or current treatment for cancer at the affected level.
19. Patient has a previous spine surgery or previous injection of cement at the vertebral levels of the surgical procedure.
20. Patient has diabetes mellitus.
21. Patient has an MRI contraindication (e.g., cerebral aneurysm clips, pacemaker, implanted biostimulators, cochlear implants, penile prosthesis).
22. Patient has an unstable spine as indicated by neurologic deficit, kyphosis greater than 30°, compression greater than 60%, translation greater than 4 mm, interspinous-process widening.
23. Pre-existing conditions contrary to either PVA or vertebroplasty, such as: a. Irreversible coagulopathy or bleeding disorder. Note regarding reversible coagulopathies: Subjects on coumadin or other anticoagulants may participate. Investigators should follow routine practices for perioperative discontinuation and re-initiation of anticoagulants; b. Any evidence of VB or systemic infection.
24. Patient has a mental deficiency (e.g., psychiatric disorders, Alzheimer's disease, presence of alcohol or drug abuse).
25. Patient is pregnant or is interested in becoming pregnant during the study duration.
26. Patient is a prisoner or ward of the state.
27. Patient expects to relocate more than 50 miles from the study center prior to completion of the study follow-up period.
28. Patient has an AO classification A2, A3, B or C type fracture.
29. Patient has hemangioma, malignant fracture, and/or multiple myeloma at the site of the index VCF.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00933036

Locations

United States, California
  Long Beach Memorial Medical Center
  Long Beach, California, United States, 90806
United States, District of Columbia
The George Washington University Hospital
Washington, District of Columbia, United States, 20037

United States, Florida
Advanced Imaging & Interventional Institute
Clearwater, Florida, United States, 33761
Orthopedic Clinic of Daytona Beach
Daytona, Florida, United States, 32117
Broward Spine Institute
Hollywood, Florida, United States, 33021
Physician's Regional Healthcare System
Naples, Florida, United States, 34119

United States, North Carolina
OrthoCarolina Research Institute
Charlotte, North Carolina, United States, 28207

United States, North Dakota
St. Alexius Medical Center
Bismarck, North Dakota, United States, 58506

United States, Wyoming
The Spine Institute - Rocky Mountain Orthopedic
Cheyenne, Wyoming, United States, 82001

Sponsors and Collaborators
Crosstrees Medical Inc.

Investigators
Study Chair: Frank M Phillips, MD  Rush University Medical Center

More Information
No publications provided

Responsible Party: Crosstrees Medical Inc.
ClinicalTrials.gov Identifier: NCT00933036  History of Changes
Other Study ID Numbers: G080175
Study First Received: July 5, 2009
Last Updated: January 21, 2014
Health Authority: United States: Food and Drug Administration

Keywords provided by Crosstrees Medical Inc.:
Osteoporosis  Kyphoplasty
VCF  Vertebral fracture
PVA  Pathologic fracture
Vertebroplasty  Vertebral augmentation

Additional relevant MeSH terms:
Fractures, Bone  Bone Diseases, Metabolic
Fractures, Spontaneous  Musculoskeletal Diseases
Osteoporosis  Wounds and Injuries
Bone Diseases

ClinicalTrials.gov processed this record on July 16, 2015