A randomised sham controlled trial of vertebroplasty for painful chronic osteoporotic vertebral fractures

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To compare pain relief after PV with a sham intervention in selected patients with a chronic osteoporotic VCF (three months or longer) using the same strict inclusion criteria as in VERTOS II an IV. Secondary outcome measures are back pain related...

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

Summary

ID

NL-OMON47294

Source
ToetsingOnline

Brief title
VERTOS V

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
osteoporotic vertebral fracture, vertebral compression fracture

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: osteoporosis, percutaneous, vertebral fracture, vertebroplasty

Outcome measures

Primary outcome

Primary outcome will be pain relief at 1 day, 1 week, and 1,3, 6 and 12 months. The questionnaire consist of the VAS score and questions about use of pain medication, pain location, and pain type. Other medical treatment and visits to alternative medical specialists, GP's and physical therapists are recorded and compared between groups. Patients are asked to fill out the VAS score and use of analgesics is recorded on a daily basis during the first month after randomization.

Secondary outcome

Back pain related disability as measured with the Roland Morris Disability (RMD) Questionnaire. The RMD questionnaire is a disability questionnaire that measures the functional status of patients with back pain.

The Qualeffo is developed specifically for patients with osteoporosis. This questionnaire consists of 41 questions. Description: QOL as measured with the Questionnaire of the European Foundation for Osteoporosis (Qualeffo). The Qualeffo is developed specifically for patients with osteoporosis. This questionnaire consists of 41 questions about: pain, physical function, social function, general health perception, and mental function. The Qualeffo score ranges from 0 (best quality of life) to 100 (worst quality of life). This questionnaire will be completed at five measurement moments (before and at 1,

3, 6 and 12 months after the procedure).

Study description

Background summary

The standard care in patients with a painful osteoporotic vertebral compression fracture (VCF) is conservative therapy. Percutaneous vertebroplasty (PV), a minimally invasive technique, is a relatively new treatment option. Recent randomized controlled trials (RCT) provide conflicting results: two sham-controlled studies showed no benefit of PV while an unmasked but controlled RCT (VERTOS II) found effective pain relief at acceptable costs in patients with acute VCFs. A still ongoing masked RCT (VERTOS IV) focuses on acute VCFs defined as <= 6 weeks. VERTOS III focused on conservative treatment and found that half of patients still had disabling pain after 3 months or longer. These patients with sustained pain after 3 months may benefit from PV.

Study objective

To compare pain relief after PV with a sham intervention in selected patients with a chronic osteoporotic VCF (three months or longer) using the same strict inclusion criteria as in VERTOS II an IV. Secondary outcome measures are back pain related disability and quality of life.

Study design

Primary Purpose: Treatment
Study Phase: Phase 3
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Single Blind (Subject)
Allocation: Randomized
Enrollment: 94 [Anticipated]

Intervention

Procedure/Surgery: percutaneous vertebroplasty
Using fluoroscopic guidance, the practitioner infiltrates the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae with 1% lidocaine and infiltrates the periosteum of the pedicles with 0.25% bupivacaine (marcaine. For the vertebroplasty procedure, 11-gauge or 13-gauge needles are passed into the central aspect of the target vertebra or vertebrae. Bone cement is prepared on the bench and injected under constant fluoroscopy into the vertebral body. Injection is stopped when the PMMA reaches to the

posterior aspect of the vertebral body or leaks into an extraosseous space, such as the intervertebral disk or an epidural or paravertebral vein.

Procedure/Surgery: Sham procedure
Using fluoroscopic guidance, the practitioner infiltrates the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae with 1% lidocaine and infiltrates the periosteum of the pedicles with 0.25% bupivacaine (marcaine. During the sham intervention, verbal and physical cues, such as pressure on the patient's back, are given, and the methacrylate monomer is opened to simulate the odor associated with mixing of cement, but the needle is not placed and cement is not injected.

Study burden and risks

not applicable

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

•VCF on X-ray of the spine (minimal 15% loss of height)
•level of VCF Th5 or lower
•back pain <= 6 weeks at time of X-ray
•>= 50 years of age
•bone edema on MRI of the fractured vertebral body
•focal tenderness on VCF level
•decreased bone density T-scores <= -1

Exclusion criteria

•severe cardio-pulmonary condition
•untreatable coagulopathy
•systemic or local infection of the spine (osteomyelitis, spondylodiscitis)
•suspected alternative underlying disease (malignancy)
•radicular and/or cauda compression syndrome
•contra-indication for MRI

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2013

Enrollment:	94
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-03-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)
Approved WMO Date:	18-05-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
ClinicalTrials.gov	NCT01200277
CCMO	NL44553.008.13

Study results

Date completed:	03-09-2020
Actual enrolment:	80