

Investigational vertebroplasty efficacy and safety trial: a sham-controlled trial of percutaneous vertebroplasty

Submission date 10/10/2003	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/11/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/04/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00068822

Secondary identifying numbers

Study information

Scientific Title

INvestigational Vertebroplasty Efficacy and Safety Trial: a sham-controlled trial of percutaneous vertebroplasty

Acronym

INVEST

Study objectives

Vertebroplasty is a procedure used to stabilise broken vertebrae, the bones that form the spine. This study will evaluate the effectiveness of vertebroplasty for the treatment of fractures due to osteoporosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Osteoporosis with painful, crushed or broken vertebra (1 or 2 levels)

Interventions

Participants in this study will be randomly assigned to receive either percutaneous vertebroplasty or a sham procedure (placebo control group). Participants may have up to 2 spinal levels treated. Participants will be enrolled in the study for 1 year and will have study

visits at entry and Months 1 and 12. There will also be phone visits at Days 1, 2, 3, and 14 and Months 3 and 6. After Month 1, crossover from the placebo group to the vertebroplasty group will be allowed.

Intervention Type

Procedure/Surgery

Primary outcome measure

Back-specific functional status using Roland Scale at the one-month time frame.

Secondary outcome measures

Health status outcome using 36-item Short Form health survey (SF-36).

Overall study start date

01/12/2003

Completion date

01/12/2008

Eligibility**Key inclusion criteria**

1. Over 50 years old
2. Confirmed osteoporosis or osteopenia
3. Painful vertebral fracture
4. Refractory to medical therapy
5. No previous vertebroplasty or kyphoplasty
6. No infections or immunocompromised patients

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

294

Key exclusion criteria

1. Malignant tumour or spinal canal compromise
2. Local or systemic infection
3. Pregnancy
4. Hip fracture

Date of first enrolment

01/12/2003

Date of final enrolment

01/12/2008

Locations

Countries of recruitment

United States of America

Study participating centre

200 1st Street SW

Rochester, MN

United States of America

55905

Sponsor information

Organisation

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (National Institutes of Health [NIH]) (USA)

Sponsor details

Bethesda

Maryland

United States of America

20810

Sponsor type

Government

Website

<http://www.niams.nih.gov/>

ROR

<https://ror.org/006zn3t30>

Funder(s)

Funder type

Government

Funder Name

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (National Institutes of Health [NIH]) (USA) (ref: AR49373-01)

Alternative Name(s)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Arthritis & Musculoskeletal & Skin Diseases, Instituto Nacional de Artritis y Enfermedades Musculoesqueléticas y de la Piel, NIAMS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Results article	results	06/08/2009	11/04/2019	Yes	No
Results article	results	01/10/2013	11/04/2019	Yes	No