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

Submission date Recruitment status [X] Prospectively registered 10/10/2003 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 11/11/2003 Completed [X] Results [] Individual participant data Last Edited Condition category Musculoskeletal Diseases 11/04/2019

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT) NCT00068822

Protocol serial number AR49070-01

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Research institutes and centers

Location

United States of America

Results and Publications

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?

<u>Results article</u> 06/08/2009 11/04/2019 Yes No

results

results

<u> </u>	Results article		01/10/2013	11/04/2019	Yes	No
<u> </u>	Basic results				No	No
<u> </u>	Participant information sheet	Participant information sheet 1	11/11/2025	11/11/2025	No	Yes