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

Submission date
10/10/2003

Recruitment status
No longer recruiting

Registration date
11/11/2003

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

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