Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Short term clinical outcome of percutaneous vertebroplasty

Protocol summary

Summary

Percutaneous vertebroplasty under imaging guide will be conducted during a 15 months period in Emam Reza Hospital of Tabriz for about 30 patients with osteoporotic compression fracture, painful hemangioma, metastasis and multiple myeloma of vertebral bodies. Before and after procedure pain and functional disability of patients willbe measured by Visual Analogue Scale and Oswestry low back pain Questionare. Any complication such as leakage of cement and canal stenosis will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902033778N1**
Registration date: **2010-05-20, 1389/02/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-05-20, 1389/02/30

Registrant information

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Tabriz Univesity of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research department of Tabriz University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2011-08-22, 1390/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short term clinical outcome of percutaneous vertebroplasty

Public title

short term clinical outcome of percutaneous vertebroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: -age over 50 years -osteoporotic compression fracture of vertebrae -painful vertebral hemangioma -painful vertebral metastasis -painful vertebral involvement by multiple myeloma exclusion criteria: -new vertebral fractures(less than 2 weeks) -old vertebral fractures(more than one year) -sever compression of vertebral body(reduction of more than 80% percent of height of the vertebra) -myelopathy -focal neurologic defects -bleeding disorders

Age

From **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
local ethic committee
Street address
tabriz university of medical sciences
City
Tabriz
Postal code
Approval date
2010-02-23, 1388/12/04
Ethics committee reference number
5/4/9300

Health conditions studied

1

Description of health condition studied
Metastasis to vertebrae with or without compression
ICD-10 code
C79.5
ICD-10 code description
metastasis to vertebrae

2

Description of health condition studied
Osteoporosis with compression fracture
ICD-10 code
M80
ICD-10 code description
osteoporosis with compression fracture

3

Description of health condition studied
Multiple Myeloma of vertebrae with or without compression
ICD-10 code
M82.0
ICD-10 code description
Multiple Myeloma of vertebrae

4

Description of health condition studied
Hemangioma of vertebrae with or without compression
ICD-10 code
D18.0
ICD-10 code description
hemangioma of vertebrae

Primary outcomes

1

Description
Pain
Timepoint
one month after cement injection
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Functional disability after vertebroplasty
Timepoint
immediately , one week and one month after injection of cement
Method of measurement
Oswestry Low Back Pain Questionare

Intervention groups

1

Description
cement injection in vertebral body under guidance of CT scan
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Shahrzad Zarayan
Street address
golgasht street
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research department of Tabriz university of medical sciences
Full name of responsible person
Dr. Ostad Rahimi
Street address
Education Building- Tabriz university
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research department of Tabriz university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty