

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The comparison of results of PV (percutaneous vertebroplasty) and conservative treatment in patients with osteoporotic VCF (vertebral compression fractures)

#### Protocol summary

##### Summary

This study, which was performed as a double blind randomized and controlled clinical trial, aimed to evaluate the efficacy of percutaneous vertebroplasty (PV) for controlling pain and improving the quality of life (QOL) as compared to the optimal medical treatment (OMT) in vertebral compression fractures (VCFS). 85 patients were randomly divided into two groups, a control group including 45 patients who were treated by optimal medical therapy and a study group including 40 patients who underwent PV for vertebral fractures beside the OMT for preventing of osteoporosis progress. Patients were evaluated by radiography, MRI and CTS and were under 1 week, 2, 6, 12, 24 and 36 months of clinical examinations. All patients with osteoporotic VCF and a height loss of the vertebral body (10-70%), low back pain in the clinical examination, progressive mild deformity, no response to the conventional medical therapy were included for performing PV and 1-3 cc polymethylmethacrylate was injected into the vertebral body according to the fracture type and vertebral condition by specific devices such as Technimed, France or MENDEC Spine Kit, Verona, Italia ([www.tecres.it](http://www.tecres.it)) as the intervention. Patients with coagulation defects, local or systemic infection, neural disorders, defect in the posterior wall of the vertebral body, painless VCF, severe spinal deformity were also excluded. Radiography was also taken at 2 and 6 months, 1, 2 and 3 years after the beginning of the treatment to show a decrease in the treatment period and medical expenses in the PV group in comparison with the OMT group

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138804252193N1**

Registration date: **2009-11-10, 1388/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-11-10, 1388/08/19

##### Registrant information

###### Name

Majid Reza Farrokhi

###### Name of organization / entity

Shiraz Neurosciences Research Center, Shiraz  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1623 4508

###### Email address

neuroscien@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz Neurosciences Research Center-Vice Chancellor  
for Research Affairs of Shiraz University of Medical  
Sciences

##### Expected recruitment start date

2005-12-21, 1384/09/30

##### Expected recruitment end date

2008-12-20, 1387/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The comparison of results of PV (percutaneous vertebroplasty) and conservative treatment in patients with osteoporotic VCF (vertebral compression fractures)

## Public title

The comparison of results of PV (percutaneous vertebroplasty) and conservative treatment in patients with osteoporotic VCF (vertebral compression fractures)

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: osteoporotic VCF patients with a height loss of the vertebral body (10-70 percents), associated with low back pain in clinical examination, progressive mild deformity, presenting no response to the optimal medical therapy Exclusion criteria: coagulation disorders, local or systemic infection, neural disorders, defect in the posterior wall of the vertebral body, painless VCF (vertebral compression fractures), severe deformity

## Age

From **30 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **85**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice-Chancellor for Research Affairs, Shiraz University of Medical Sciences

##### Street address

Central Building of Shiraz University of Medical Sciences, Zand boulevard, Shiraz

##### City

Shiraz

##### Postal code

713451978

## Approval date

2009-09-26, 1388/07/04

## Ethics committee reference number

CT-88-4726

## Health conditions studied

### 1

#### Description of health condition studied

Osteoporotic Vertebral Compression Fractures

#### ICD-10 code

S32.0

#### ICD-10 code description

Fracture of Lumbar Vertebra

## Primary outcomes

### 1

#### Description

Fast treatment of osteoporotic vertebral compression fractures by PV (percutaneous vertebroplasty)

#### Timepoint

one week, 2, 6, 12, 24, and 36 months after intervention

#### Method of measurement

Radiography

## Secondary outcomes

### 1

#### Description

Medical expenses

#### Timepoint

2 months, 6 months, 1 year, 2 years, and 3 years after intervention

#### Method of measurement

Cost of medical care

## Intervention groups

### 1

#### Description

Injecting 1-3cc (based on the type of vertebral fractures) of polymethylmethacrylate by PV technique

#### Category

Treatment - Other

### 2

#### Description

Long rest, using painkillers and orthotic brace, prescription of calcium at least 500 mg twice a day and Alendronate

#### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Chamran Hospital

**Full name of responsible person**

Dr. Majid Reza Farrokhi

**Street address**

Shiraz Neurosciences Research Center, Chamran Hospital, Shiraz

**City**

Shiraz

## 2

### Recruitment center

**Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Dr. Majid Reza Farrokhi

**Street address**

Zand st., Shiraz

**City**

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**Name of organization / entity**

Shiraz Neurosciences Research Center, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Majid Reza Farrokhi

**Position**

Neurosurgeon, Fellowship of Spinal Surgery, Director of Shiraz Neurosciences Research Center

**Other areas of specialty/work****Street address**

Shiraz Neurosciences Research Center, Chamran Hospital

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Vice-Chancellor for Research Affairs of Shiraz University of Medical Sciences, Apadana Tajhiz Gostar

**Street address**

Vice-Chancellor for Research Affairs, central building of Shiraz University of Medical Sciences, Zand boulevard, Shiraz

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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

### Contact

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz Neurosciences Research Center, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Majid Reza Farrokhi

**Position**

Neurosurgeon, Fellowship of Spinal Surgery

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## Person responsible for updating data

### Contact

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Shiraz Neurosciences Research Center, Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

The Expert of Research Affairs of the Center

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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*