

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical and radiological outcomes of standalone polymethylmethacrylate vertebroplasty versus posterior spinal fixation in the treatment of patients with thoracolumbar burst fractures

Protocol summary

Study aim

Is vertebroplasty an effective and sufficient treatment for single-level burst thoracolumbar fractures?

Design

We will perform a prospective single-blind, randomized trial in which 52 patients with burst thoracolumbar fractures will be enrolled.

Settings and conduct

Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Traumatic fracture, age between 18 to 65 years, burst fracture (40-60% height reduction; 20-40% canal compromise; kyphotic angulation 20 to 40 degrees), hemodynamic stability, fracture below T6 level, fracture in the last 2 weeks, intact neurological exam, one or two level fractures

Intervention groups

Intervention group: posterior spinal fixation in the treatment of patients with thoracolumbar burst fractures
Intervention group: standalone polymethylmethacrylate vertebroplasty in the treatment of patients with thoracolumbar burst fractures

Main outcome variables

Radiologic outcomes include postoperative angulation and the correction of height reduction. The severity of postoperative pain is evaluated using the VAS. quality of life (QOL) is evaluated by a questionnaire based on the Oswestry Disability Index (ODI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180604039980N2**

Registration date: **2021-03-21, 1400/01/01**

Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**

Update count: **0**

Registration date

2021-03-21, 1400/01/01

Registrant information

Name

Majid Reza Farrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3623 4508

Email address

snrc@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and radiological outcomes of standalone polymethylmethacrylate vertebroplasty versus posterior spinal fixation in the treatment of patients with thoracolumbar burst fractures

Public title

Standalone vertebroplasty versus posterior spinal fixation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Traumatic fracture Age between 18 to 65 years Burst fracture (40-60% height reduction, 20-40% canal compromise, kyphotic angulation 20 to 40 degrees) Hemodynamic stability Fracture below T6 level Fracture in the last 2 weeks Intact neurological exam One or two level fractures

Exclusion criteria:**Age**

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

We will perform a prospective single-blind, randomized case-controlled trial in which 52 patients with thoracolumbar burst fractures will be enrolled. A general practitioner not only will assess 52 patients for eligibility, but also will evaluate baseline characteristics of eligible patients before randomization. Written informed consent will be obtained from all patients before operation. Eligible participants will be randomly assigned to two groups by opening sealed envelopes. The envelopes will be prepared beforehand and sorted randomly by using random allocation software (computerized random number generators). Randomization will be performed by a neurosurgery resident after the inclusion of the patients into the study by the surgeon. The patient will draw one of the two envelopes indicating surgical treatment with either Standalone Polymethylmethacrylate Vertebroplasty or Posterior Spinal. The patients will be randomly allocated to one of two groups: group I: standalone percutaneous cement augmentation in the fractured level(s) group II: posterior pedicular screw fixation in the fractured level(s).

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analysts and evaluators will be blind in this study, therefore it will be a single-blind study.

Placebo

Not used

Assignment

Parallel

Other design features

Fifty-two patients with thoracolumbar burst fractures are eligible for participation. The patients will randomly be allocated to two groups: group A or vertebroplasty (n=26), and group B or pedicular screw fixation (n=26).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SUMS.REC.1398.378

Health conditions studied**1****Description of health condition studied**

Clinical and radiological outcomes of standalone polymethylmethacrylate vertebroplasty versus posterior spinal fixation in the treatment of Patients with thoracolumbar burst fractures

ICD-10 code

S22.001A

ICD-10 code description

Stable burst fracture of unspecified thoracic vertebra, initial encounter for closed fracture

Primary outcomes**1****Description**

Spinal kyphosis

Timepoint

Preoperatively, early postoperatively and at 2 and 6 months after the surgery

Method of measurement

Measure the degree of spinal angulation

2**Description**

Vertebral height

Timepoint

Preoperatively, early postoperatively and at 2 and 6 months after the surgery

Method of measurement

Measure the vertebral height

3

Description

Pain measurement

Timepoint

Two and six months after the operation

Method of measurement

The pain VAS (Visual Analogue Scale) is a unidimensional measure of pain intensity.

4

Description

Low back pain disability measurement

Timepoint

Six months after the operation

Method of measurement

For measuring the low back pain disability, the Oswestry Disability Index (ODI) is used.

Secondary outcomes

1

Description

Pain score according to VAS (Visual Analogue Scale)

Timepoint

Two and six months after the operation

Method of measurement

The Visual Analogue Scale (VAS) consists of a straight line with the endpoints defining extreme limits such as "no pain at all" and "pain as bad as it could be". The patient is asked to mark his pain level on the line between the two endpoints. The distance between "no pain at all" and the mark then defines the subject's pain.

2

Description

Oswestry Disability Index (ODI)

Timepoint

Six months after the operation

Method of measurement

The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for low back pain.

Intervention groups

1

Description

Intervention group: standalone polymethylmethacrylate vertebroplasty in the treatment of patients with thoracolumbar burst fractures

Category

Treatment - Surgery

2

Description

Intervention group: posterior spinal fixation in treatment

in the treatment of patients with thoracolumbar burst fractures

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Polyclinic

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

2nd Floor, Motahari Polyclinic, Namazee Square, Shiraz

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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

Street address

Vice-Chancellor for Research Affairs, Central building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

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

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Shiraz Neurosciences Research Center, Chamran Hospital, Chamran Blvd., Shiraz

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Majid Reza Farrokhi

Position

Neurosurgeon, Fellowship of spinal surgery, Director of Shiraz Neurosciences Research Center

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Negar Nejabat

Position

Health Researcher

Latest degree

Master

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nejabatnegar@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Standalone polymethyl methacrylate (PMMA) vertebroplasty versus posterior spinal fixation in the treatment of burst thoracolumbar fractures with regard to clinical and radiologic outcomes. Radiologic outcomes include postoperative angulation and the correction of height reduction. The severity of postoperative pain is evaluated using the VAS. quality of life (QOL) is evaluated by a questionnaire based on the Oswestry Disability Index (ODI).

When the data will become available and for how

long

After the publication of the results.

To whom data/document is available

All readers

Under which criteria data/document could be used

All data of the patients will be available to the corresponding author of this proposal. For any query on the data of the patients in this study, you can contact

Shiraz Neuroscience Research Center and pose your request to the corresponding author of this study.

From where data/document is obtainable

Shiraz Neuroscience Research Center

What processes are involved for a request to access data/document

Contact Shiraz Neuroscience Research Center

Comments