Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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 ow 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
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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
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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Neurosurgeon, Fellowship of spinal surgery, Director of Shiraz Neurosciences Research Center

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Negar Nejabat

Position
Health Researcher

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Master

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Neurology

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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