Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of posterior-fusion instrumentation with and without balloon kyphoplasty and polymethyl methacrylate cement injection on the radiological results of traumatic fractures of thoraco-lumbar vertebrae

Protocol summary

Study aim

Comparison of posterior-fusion instrumentation with and without balloon kyphoplasty and polymethyl methacrylate cement injection on the radiological results of traumatic fractures of thoraco-lumbar vertebrae

Design

A open-label, randomized clinical trial study with parallel groups and phases 3 on 50 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct

An open-label , randomized clinical trial study with parallel groups and phases 3 on 50 patients. Randomization will be done with the block randomization method using Random allocation software.

Participants/Inclusion and exclusion criteria

In this study, 50 patients ≥18 years presenting with an acute traumatic thoracolumbar burst fracture (AO type A3 or A4) within five days of injury, without neurological deficit will be included. Exclusion criteria will be fractures due to cancer, severe osteoporosis, thyroid disorders, a Glasgow Coma Scale score of less than 15 at admission and the presence of any pre-existing spinal pathology.

Intervention groups

Patients in intervention group undergoing a combined procedure consisting of transpedicular balloon kyphoplasty followed by short-segment posterior instrumentation. Patients in control group undergoing conventional short-segment posterior instrumentation using a pedicle screw–rod system.

Main outcome variables

This open-label randomised clinical trial will be conducted on patients with an acute traumatic thoracolumbar burst fracture who referring to Urmia Imam Khomeini Hospital. Patients will be assigned into conventional Short-segment pedicle screw instrumentation with and without balloon kyphoplasty.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230520058233N3**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **prospective**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date

2026-04-29, 1405/02/09

Registrant information

Name

Peyman Gholipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

gholipour.p@umsu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of posterior-fusion instrumentation with and without balloon kyphoplasty and polymethyl methacrylate cement injection on the radiological results of traumatic fractures of thoraco-lumbar vertebrae

Public title
Investigating the posterior-fusion instrumentation with and without balloon kyphoplasty on the radiological res

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients over 18 years Patients with an acute traumatic thoracolumbar burst fracture (AO type A3 or A4) Patients who referring within five days of injury without neurological deficit

Exclusion criteria:
Patients with fractures due to cancer and severe osteoporosis Thyroid disorders Glasgow Coma Scale score of less than 15 at admission The presence of any pre-existing spinal pathology

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Imam Khomeini Khomeini Hospital, Urmia University of Medical Science

Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.

City
Urmia

Province
West Azarbaijan

Postal code
57157-89397

Approval date
2024-07-10, 1403/04/20

Ethics committee reference number
IR.UMSU.HIMAM.REC.1403.043

Health conditions studied

1

Description of health condition studied
Acute traumatic thoracolumbar fractures

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cobb angle

Timepoint
Before and one year after intervention

Method of measurement
Radio graphy

2

Description
Anterior vertebral body height (ABH

Timepoint
Before and one year after intervention

Method of measurement
Radio graphy

3

Description
Posterior vertebral body height (PBH)

Timepoint
Before and one year after intervention

Method of measurement
Radio graphy

Secondary outcomes

1

Description
Infection of site surgery

Timepoint
One year after intervention

Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group: Patients in this group undergoing a combined procedure consisting of transpedicular balloon kyphoplasty followed by short-segment posterior instrumentation.First Balloon kyphoplasty wl'll be performed at the level of the fractured vertebra. After standard preparation, inflatable bone tamps will inserted via a transpedicular approach and gradually inflated under fluoroscopic guidance to restore endplate height and create an intravertebral cavity. The cavity will subsequently filled with polymethylmethacrylate (PMMA) cement under continuous fluoroscopic monitoring.Following cement augmentation, short-segment posterior instrumentation will performed using a pedicle screw–rod system.
Category
Treatment - Surgery

2

Description
Control group: Patients in this group undergoing conventional short-segment posterior instrumentation using a pedicle screw–rod system.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini Hospital
Full name of responsible person
Dr.Peman Gholipour
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.
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Gholipour.p@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences., Resalat street., Jahad Blvd., Urmia, Iran.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Peyman Gholipour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There are no additional information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable