

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 will be performed at the level of the fractured vertebra. After standard preparation, inflatable bone tamps will be inserted via a transpedicular approach and gradually inflated under fluoroscopic guidance to restore endplate height and create an intravertebral cavity. The cavity will subsequently be filled with polymethylmethacrylate (PMMA) cement under continuous fluoroscopic monitoring. Following cement augmentation, short-segment posterior instrumentation will be 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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