

# 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  $\geq 18$  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.

##### City

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##### Province

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##### Postal code

57157-89397

##### Phone

+98 44 3345 7286

##### Email

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.

##### City

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##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 4897

##### Email

gholipour.p@umsu.ac.ir

#### 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Peyman Gholipour

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Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Full name of responsible person**

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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