

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Functional Recovery following Early Kyphoplasty versus Conservative Management in Stable Thoracolumbar Fractures in Parachute Jumpers

#### Protocol summary

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#### Summary

The aim of the current study is to compare the functional recovery between early kyphoplasty and conservative care in paratroopers with stable thoracolumbar fractures. We will include 70 paratroopers aging 18 to 45 years with stable thoracolumbar fractures presenting less than 30 days after trauma. Old fractures and those requiring surgery will be excluded. Patients would be randomly assigned to two study groups to undergo percutaneous balloon kyphoplasty (n=35) or conservative care (n=35) by applying orthosis for 3 months. Patients would be followed for 6 months and would be evaluated clinically using visual analogue scale and Oswestry disability index.

#### Recruitment status

**Recruitment complete**

#### Funding source

Shiraz University of Medical Sciences

#### Expected recruitment start date

2012-03-01, 1390/12/11

#### Expected recruitment end date

2015-01-01, 1393/10/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201611172445N3**

Registration date: **2016-12-06, 1395/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2016-12-06, 1395/09/16

#### Registrant information

#### Name

Fariborz Ghaffarpasand

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 71 3647 4259

#### Email address

#### Scientific title

Functional Recovery following Early Kyphoplasty versus Conservative Management in Stable Thoracolumbar Fractures in Parachute Jumpers

#### Public title

Kyphoplasty versus Conservative Therapy with Brace for Vertebral Fractures

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Military parachute jumper; age between 18 and 45 years; acute stable thoracolumbar fractures (T10-L2); stable fractures classifying as A1 and A2 according to AOSpine thoracolumbar spine injury classification system; intact posterior ligamentous complex (PLC); intact neurological exam; acute fracture being confirmed by hypo- and hyper-intense signal change in the vertebral body in T1- and T2-weighted MRI, respectively. Exclusion criteria: Unstable thoracolumbar fractures; ruptured PLC; neurological deficit; being referred later than 30-days of the injury; vertebral angulation of more than 35 degrees; decreased vertebral height of more than 50%; pre-injury neurological deficits;

previous thoracolumbar fractures; previous spinal procedures; metabolic bone diseases; history of anaphylactic or drug reactions.

#### Age

From **18 years** old to **45 years** old

#### Gender

Male

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

###### Street address

Ethics Committee of Shiraz University of Medical Sciences, Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Avenue

###### City

Shiraz

###### Postal code

##### Approval date

2016-09-02, 1395/06/12

##### Ethics committee reference number

IR.SUMS.MED.REC.1395.578

### Health conditions studied

#### 1

##### Description of health condition studied

Fracture of thoracic vertebra

##### ICD-10 code

S22.0

##### ICD-10 code description

Fracture of thoracic vertebra

#### 2

##### Description of health condition studied

Fracture of lumbar vertebra

##### ICD-10 code

S32.0

##### ICD-10 code description

Fracture of lumbar vertebra

### Primary outcomes

#### 1

##### Description

Pain intensity

##### Timepoint

Baseline, 1 month, 3 months, 6 months

##### Method of measurement

Visual Analogue Scale (VAS)

#### 2

##### Description

Disability

##### Timepoint

Baseline, 1 month, 3 months, 6 months

##### Method of measurement

Oswestry disability index (ODI)

### Secondary outcomes

#### 1

##### Description

Days absence from work

##### Timepoint

6 months

##### Method of measurement

Days

#### 2

##### Description

Duration for starting parachute jumping

##### Timepoint

6 months

##### Method of measurement

Days

### Intervention groups

#### 1

##### Description

Percutaneous Balloon Kyphoplasty of the fracture level and injection of 5cc bone cement

##### Category

Treatment - Surgery

#### 2

##### Description

Conservative therapy by applying thoracolumbar orthosis for 3 months.

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital of AJA University of Medical Sciences

**Full name of responsible person**

Mohammad Sadegh Masoudi

**Street address**

**City**

Tehran

2

**Recruitment center**

**Name of recruitment center**

Shiraz 576 Artesh Hospital

**Full name of responsible person**

Mohammad Sadegh Masoodi

**Street address**

**City**

Shiraz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor of Research, Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Basir Hashemi

**Street address**

Vice Chancellor of Research, Floor 7, Shiraz University of Medical Sciences, Zand Avenue, Shiraz

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor of Research, Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fariborz Ghaffarpasand

**Position**

Resident

**Other areas of specialty/work**

**Street address**

Neurosurgery Department Office, Namazi Hospital, Namazi Square

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*