Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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.

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)

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ghafarf@sums.ac.ir

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

Scientific title

Functional Recovery following Early Kyphoplasty versus Conservative Management in Stable Thoracuolumbar 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 Baloon Kyphoplasty of the fracture level and injection of 5cc bone cement

Category
Treatment - Surgery

2

Description

Conservative therapy by applying thoracolumabr 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

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Person responsible for scientific inquiries

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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