

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of neurological and Radiological results of Posterior instrumentation with and without Distraction for thoracolumbar fractures

Protocol summary

Study aim

Evaluation of neurological and Radiological results of Posterior instrumentation with and without Distraction for thoracolumbar fractures

Design

This triple-blind study was performed on patients with thoracolumbar fractures in the control group at the end of the operation without distraction force fixation will be done, but in the trail group before fixation, the distraction force will be applied to the screws and then fixation will be done.

Settings and conduct

This study will be randomized clinical trial study on 60 patients with thoracolumbar vertebral fractures due to spinal cord trauma who refer to Imam Reza Hospital in Tabriz. Patients participating in the study will be done posterior fusion with pedicle screw. then patients is divided into two groups, A or B, which have already been identified. The patient will not be aware of the type of surgery method, but the head nurse of the trauma department of Imam Reza Hospital in Tabriz and the operating room staff will be aware of this and will stick one of the A or B stickers in the patient's file and after transferring the patient to the operating room. One of the two modes of observation will be performed according to the relevant default (which the operating room staff is aware of).

Participants/Inclusion and exclusion criteria

1- Spinal fractures due to the type of fracture 2- Having indications for surgery
Criteria for leaving the study: 1- Having pathological fractures 2- Fracture in several vertebrae 3- Simultaneous head trauma

Intervention groups

trail group: Patients who undergo stretching after screwing and then fixation
Control group: After screwing, you apply without applying fixation

Main outcome variables

Anterior vertebral fracture height, anterior vertebral collapse percentage, posterior vertebral fracture height,

vertebral posterior vertebral collapse, local kyphosis angle, neurological symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200615047777N1**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **prospective**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

peyman gholipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 1333 8507

Email address

gholipoorpeyman5892@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-11, 1399/04/21

Expected recruitment end date

2021-07-12, 1400/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of neurological and Radiological results of Posterior instrumentation with and without Distraction for thoracolumbar fractures

Public title

Investigating two modes of traction and non-traction use of the vertebrae in the postoperative instrumentation method in patients with traumatic fractures of the lumbar-thoracic vertebrae in radiological results and improvement in neurological symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Spinal fractures due to the type of fracture - a fracture that will be diagnosed based on the three-column model of Denis in the CT Scan and attention to the damaged columns, which will be interpreted by the neurosurgery resident. Having an indication for surgery, which is an indication of decision making for surgery based on the Thoracolumbar injury classification severity score (TLCS) scoring system. In short, it includes three independent factors or computed tomography scans and MRI findings and findings related to neurological examination. Having a conscious consent to participate in the study

Exclusion criteria:

Having pathological fractures Fracture in several vertebrae The trauma of the head at the same time and the neurological condition of the patient should be such that it is not possible to - Having a nervous defect before spinal trauma Shear fracture is a type of fracture

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the study will be as follows by software R version 3.2, 60 random sequences A and B that have 30 modes A and 30 modes B and their labels will be prepared, which is one of the cases related to the surgical method with It will be stretching and will be one of the cases related to the surgical method without stretching

Blinding (investigator's opinion)

Triple blinded

Blinding description

The researcher or patient will not be aware of the type of surgery method, but the head of the trauma department

of Imam Reza Hospital in Tabriz and the operating room staff will be aware of this and will stick one of the A or B stickers in the patient's file and after transferring the patient to the room. The operation will be performed by observing one of the two cases according to the relevant default (which the operating room staff is aware of). Knowing which surgery method was chosen will examine the patient neurologically and will record radiological criteria for the patient. The statistical analyzer is also unaware of the type of surgical procedure performed, and based on this, the study will be blinded three times. After the analysis, the head of type A and B methods will be asked

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz Medical School

Street address

Golgasht Street / Tabriz University of Medical Sciences / Central Building No. 2 / Third Floor

City

Tabriz

Province

East Azarbaijan

Postal code

04133357310

Approval date

2018-10-08, 1397/07/16

Ethics committee reference number

IR.TBZMED.REC.1397.596

Health conditions studied**1****Description of health condition studied**

Traumatic fractures of the thoracolumbar vertebrae

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

anterior vertebral height

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

Using a ruler in millimeters

2

Description

Percentage of anterior vertebral collapse

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

in term of percentage

3

Description

The posterior height of the vertebra is broken

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

Using a ruler and in millimeters

4

Description

Percentage of posterior vertebral collapse

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

in term of percentage

5

Description

Local kyphosis angle

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

Using conveyor and by degree

6

Description

Nervous symptoms

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

According to the Frankel scale, the division into 5 groups of A - E

7

Description

Type of surgical method

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

According to the division into A and B.

8

Description

year

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

depending on year

9

Description

Gender

Timepoint

Upon arrival and during discharge and 3 months later

Method of measurement

Depending on the gender of the man or woman

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who undergo stretching after screwing and then fixation

Category

Treatment - Surgery

2

Description

Control group: Patients who undergo screwing without fixation

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

peyman gholipor

Street address

Azadi St. Golghast St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3334 7054

Email

gholipoorpeyman5892@gmail.com

Web page address

<https://imamreza.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ali Meshkini

Street address
Golghast Street ...Azadi St

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3336 3176

Email
Meshkinia@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Moslem Shakeri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Emam Reza Hospital, Gholghasht Street, Azadi Street,

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
shakerim@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Moslem Shakeri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Emam Reza Hospital, Gholghasht Street, Azadi Stree

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
shakerim@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
peyman gholipour

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

Street address
Azadi St. Golghast St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 41 3334 7054

Email
gholipoorpeyman5892@gmail.com

Web page address
<https://imamreza.tbzmed.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available