Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the neurological and radiological results of posterior instrumentation with and without distraction for thoracolumbar fractures

Protocol summary

Study aim
Comparison of neurological and radiological results of posterior instrumentation with and without distraction for thoracolumbar fractures

Design
This study was conducted in a randomized clinical trial on 60 patients with thoracolumbar vertebral fracture resulting from spinal column trauma referring to Imam Reza Hospital in Tabriz.

Settings and conduct
This study will be carried out at Tabriz Imam Reza Hospital in the form of a triple -blind, only the head nurse will be aware of it, and the patient and the patient will be unaware of it.

Participants/Inclusion and exclusion criteria
Spinal cord sprain is due to the type of fracture; dislocation; signing informed consent to participate in the study

Intervention groups
This study was conducted as an interventional study on patients with traumatic lumbar-bone fractures referred to Imam Reza Emergency Hospital in Tabriz and the criteria for entering the study. For this purpose and according to previous studies And according to the probable number of those referring to Emam Reza Emergency Hospital in Tabriz and the constraints on entry criteria, 60 patients with entry criteria will be selected.

Main outcome variables
neurological and radiological results

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120527009878N5**
Registration date: **2019-01-03, 1397/10/13**
Registration timing: **prospective**
Last update: **2019-01-03, 1397/10/13**
Update count: **0**

Registration date
2019-01-03, 1397/10/13

Registrant information

Name
Firooz Salehpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2021-03-21, 1400/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the neurological and radiological results of posterior instrumentation with and without distraction for thoracolumbar fractures

Public title
Evaluation of neurological and radiological results of posterior instrumentation with and without distraction for thoracolumbar fractures

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with traumatic thoracolumbar fractures referring to emergency department of Imam Reza Hospital in Tabriz and undergoing surgery Have informed consent to participate in the study Indication for surgical determination that determines the surgical decision based on the Thoracolumbar injury classification severity score (TLCS). According to this scoring system, if the score is more than 4, it will have a surgical indication.

Exclusion criteria:

Pathological fractures Fractures in several bons Simultaneous head trauma and neurological condition of the patient in such a way that it is not possible to have a neurological examination at the time of admission Having a nerve defect before a spinal trauma Fractures of the type of fracture - dislocation

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the study will be chosen by R software version 3.2, 60 random sequences A and B with 30 modes A and 30 B modes, and their labels will be prepared, which is one of the scenarios related to the surgical method Stretching will be one of the conditions related to the method of stretching surgery (without the researcher or patient to know) that the chief nurse of the trauma department at Tabriz Imam Hospital Hospital and the operating room staff will be aware of this and will have one of the A or B stickers It will stick to the patient's case and after passing the patient into the operating room by observing one of the two conditions according to the default one (which the operation box is aware of) The relevant animal will be performed and after the patient is discharged, a corresponding label will be affixed to the patient's case summary. Three months later the examiner, without knowing which surgical procedure was selected, examined the patient and submitted radiological records to the patient. It will be unclear whether the statistical method is of a surgical method. Accordingly, the study will be blinded three times and, after analysis, will be asked from the head nurse the method A and B will be asked.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Accordingly, the study will be triple blinded and, after analysis, will be asked from the head nurse to clarify the codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tabriz University of Medical Sciences

Street address

Emam Reza hospital, Golgasht ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2018-10-07, 1397/07/15

Ethics committee reference number

IR.TBZMED.REC.1397.596

Health conditions studied

1

Description of health condition studied

traumatic thoracolumbar fractures Because of its traumatic nature, it is not one of the pathological diseases and fractures

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Radiological variable: Anterior hemorrhage of the vertebrae and anterior collapse percentage of the vertebrae

Timepoint

Before and after surgery and referral 3 months later

Method of measurement

By simple radiography, the anterior height of the nut is expressed in millimeters. In order to measure the collapse, the anterior height of the broken nut is divided by the height of the anterior vertebrae by 100 times.

2

Description
Radiographic variables: Posterior height of the broken nut and the percentage of posterior collapse of the vertebra
Timepoint
Before and after surgery and referral 3 months later
Method of measurement
By simple radiography, the posterior height of the nut is expressed in millimeters, and for measuring the collapse of the vertebra, the posterior height of the broken nut is divided by the posterior height of the normal nut by 100.

3

Description
Clinical signs that will be expressed according to Frankl's standard.
Timepoint
Before and after surgery and referral 3 months later
Method of measurement
According to Frankl's criterion, where A means a complete loss of motor function and sensation below the level of the lesion, it means complete health.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients participating in the study will be transferred to the operating room within one to two days after diagnosis and marking, and will be anesthetized and wound on the bed in the operating room, and in the middle of the longitudinal line to reach the broken nut and The upper and lower vertebrae will be opened and then the fixation and posterior fusion will be done using a pedicure screw. At this stage, the patients will be divided into two groups: intervention and control of the distraction group.
Category
Treatment - Surgery

2

Description
Control group: Patients participating in the study will be transferred to the operating room within one to two days after diagnosis and marking, and will be anesthetized and wound in the bed of the operating room, and in the middle of the longitudinal line to achieve the broken nut, and The upper and lower vertebrae will open and then the posterior fixation and fusion will be done using a pedicure screw, and in the distraction group, the rod will not be removed and will be closed without diserection.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Peyman Gholipoor
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz medicine university
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
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Firouz Salehpour
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Latest degree
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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