

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of surgical or non-surgical treatment outcomes in patients with thoracolumbar fracture with score 4 of TLICS

Protocol summary

Summary

Aim of this study is Comparison of surgical or non-surgical treatment outcomes in patients with thoracolumbar fracture with score 4 of TLICS. This study is clinical trial and double blind. We will interne patient with trauma and thoracolumbar fracture with score 4 of TLICS in this study. We will divide 50 patient randomly in two group (intervention group: we treat 25 patient with surgery) (control group: We treat 25 patient with not surgery treatment). Not surgery treatment is including: horizontal bed rest for 5 days, standard physiotherapy, appliance bras and not severe physical body. We will follow all patients for one year after treatment. Outcome and follow is including: duration of bedridden, duration of absent for work, return for work before trauma, visual analog scale (before intervention and every 3 months to one years), radiography (before intervention and every 3 months to one years) Inclusion criteria: 18-60 years; fracture in T1 to L4; interval of trauma to bedridden less than 10 days Exclusion criteria: pregnancy; pathological and osteoporosis fracture; history of surgery in spine; ASA IV

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010920258N25**

Registration date: **2017-01-18, 1395/10/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Challore of Research , Arak University of medical Siences

Expected recruitment start date

2016-04-26, 1395/02/07

Expected recruitment end date

2017-04-27, 1396/02/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of surgical or non-surgical treatment outcomes in patients with thoracolumbar fracture with score 4 of TLICS

Public title

Comparison of surgical or non-surgical treatment outcomes in patients with thoracolumbar fracture with score 4 of TLICS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-60 years; fracture in T1 to L4; interval of trauma to bedridden less than 10 days
Exclusion criteria: pregnancy; pathological and

osteoporosis fracture; history of surgery in spine; ASA IV

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.ARAKMU.REC.1395.39

Health conditions studied

1

Description of health condition studied

Thoracic fracture

ICD-10 code

S22.0

ICD-10 code description

Fracture of thoracic vertebra

2

Description of health condition studied

Lumbar fracture

ICD-10 code

S32.0

ICD-10 code description

Fracture of lumbar vertebra

Primary outcomes

1

Description

duration of bedridden in hospital

Timepoint

after surgery

Method of measurement

day

2

Description

duration of absent for work

Timepoint

before and after surgery

Method of measurement

day

3

Description

Pain

Timepoint

before intervention and every 3 months to one years

Method of measurement

Visual Analogue Scale

4

Description

Local sagittal angles

Timepoint

before intervention and every 3 months to one years

Method of measurement

radiography

5

Description

Regional sagittal angles

Timepoint

before intervention and every 3 months to one years

Method of measurement

radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 patients are undergoing surgery.

Category

2**Description**

Control group: We treat 25 patient with not surgery treatment. Not surgery treatment is including: horizontal bed rest for 5 days, standard physiotherapy, appliance bras and not severe physical body

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Alireza Mohammadi

Street address

Valiasr hospital, Arak

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Arak 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**

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Full name of responsible person

Dr Ali Ahmadi

Position

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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