

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Sep 2026

Comparison of two methods of vertebral fixation through pedicle screwing and pedicle screwing with kyphoplasty during recovery and pain and pull out screws in patients with lumbar or dorsal vertebral fracture

Protocol summary

Study aim

Comparison of two methods of vertebral fixation through pedicle screwing and pedicle screwing with kyphoplasty during recovery and pain and pull out screws in patients with lumbar or dorsal vertebral fracture

Design

The study will be double blind and clinical trial. 40 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct

Patients with lumbar or dorsal vertebral fracture in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients candidates for lumbar or back fracture surgery, absence of underlying diseases, no history of thromboembolism, age 18 years and above, absence of pathological fracture, no history of underlying bone disease. Exclusion criteria: Unwillingness to participate in the study, death

Intervention groups

Intervention group 1: In this group, pedicle screw placement is performed. At the beginning of the surgery, the fixation level should reach a level so that the spine is exposed. Intervention group 2: Kyphoplasty will be performed along with pedicle screw placement

Main outcome variables

The average rate of Proximal Junction Kyphosis and Proximal Junction Failure, the average rate of screw loosening, the average pain, the average recovery time and return to normal life, the rate of pseudo-arthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N177**

Registration date: **2022-11-24, 1401/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-24, 1401/09/03**

Update count: **0**

Registration date

2022-11-24, 1401/09/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of vertebral fixation through pedicle screwing and pedicle screwing with kyphoplasty during recovery and pain and pull out screws in patients with lumbar or dorsal vertebral fracture

Public title
Comparison of two methods of vertebral fixation through pedicle screwing and pedicle screwing with kyphoplasty during recovery and pain and pull out screws in patients with lumbar or dorsal vertebral fracture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients candidates for lumbar or back fracture surgery Age 18 years and above
Exclusion criteria:
underlying diseases history of thromboembolism pathological fracture underlying bone disease

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
Surgery is performed by a neurosurgeon and follow-up and examination of patients is performed by a resident. And the analyzer will also be unaware of groups. The study is double-blind. It should be noted that in order to be a double-blind study, the data is collected by a specialized assistant who was unaware of the groupings.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

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Province

Markazi

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3848176941

Approval date

2022-04-03, 1401/01/14

Ethics committee reference number

IR.ARAKMU.REC.1401.006

Health conditions studied

1

Description of health condition studied

lumbar or dorsal vertebral fracture

ICD-10 code

S32.0

ICD-10 code description

Fracture of lumbar vertebra

Primary outcomes

1

Description

Average amount (Proximal Junctional Kyphosis)

Timepoint

6 months and one year after the operation

Method of measurement

Radiography

2

Description

The average rate of Proximal Junctional Failure

Timepoint

6 months and one year after the operation

Method of measurement

Radiography

3

Description

Average wear of screws

Timepoint

6 months and one year after the operation

Method of measurement

Radiography

4

Description

Mean of pain

Timepoint

1.5, 3, 6 and 12 months after surgery

Method of measurement

Pain Visual Analog Questionnaire

5

Description

average time of recovery and return to normal life

Timepoint

After surgery

Method of measurement

Physical examination

6

Description

The amount of pseudoarthrosis

Timepoint

6 months and one year after the operation

Method of measurement

Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, pedicle screw placement is done. At the beginning of the surgery, the fixation level should reach a level so that the spine is exposed. The entry point of the pedicle screw in the vertebrae of the lumbar arch is determined based on the intersection point of each of the four lines: • Pars interarticularis • Mamillary process • Lateral border of the superior articular facet • Mid transverse process The entry point of the pedicle screw in the sections The bottom of the thoracic arch is determined after determining the intersection of the middle part of the facet joint (the joint between the vertebrae) and the upper edge of the transverse process. The entry point of the screw is in the lateral and end part of this intersection. Guide points: • Lateral border of the superior facet • Lateral border of the inferior facet • Ridge of the pars interarticularis • Transverse process To split the cortex surface as an entry point, you can use drill and rongeur used. Terminal angle of the skull: a pedicle rod is used to guide the path towards the vertebral body. The correct progress of the pedicle rod in the final path of the skull depends on the contralateral transverse process and causes the hole to be created in a direction parallel to the original surface. Medial-lateral tilt: Medial-lateral tilt depends on the rotation of the vertebra and its location up to 45 degrees in L5 or 0 degrees It is approved in T5. In the case of deep

insertion, the important point is to prevent penetration into the inner part of the spinal canal and lateral or anterior penetration into the cortex of the vertebral body. Ideally, the path of the two screws should be close to each other, while only being placed in the cortex of the pedicle and its body. Screw placement: The pedicle screw with the appropriate diameter and length is selected by the surgeon using a special device completely. It is placed in the created channel and fills the entire channel. Throughout this process, radiographic images can be used to ensure the correct placement of the screw. Depending on the surgeon, a single or multi-axis screw is selected for the operation.

Category

Treatment - Surgery

2

Description

Intervention group 2: Kyphoplasty will be performed along with pedicle screw placement. After the pedicle screw placement is done, two small and special needles are inserted into the broken area using anesthesia. Then, with the help of a balloon, the structure of the spine and vertebrae is formed, and then bone cement is poured into the vertebrae to harden them. This surgery takes one hour for each broken vertebra.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Ali Nazemi Rafi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

Assistant

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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