Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of cranial and caudal pedicle screw-selective unilateral cemented versus fully reinforced pedicle screws in the lumbar spine of patients with osteoporosis a prospective randomized clinical trial.

Protocol summary

Study aim
Comparative study of selective reinforcement of unilateral cranial and caudal pedicle screws with cement versus full reinforcement of pedicle screws in the osteoporotic spine: a prospective randomized clinical trial

Design
This study is a randomized, prospective, and unblinded clinical trial.

Settings and conduct
This study is a prospective, randomized, unblinded clinical trial that will be conducted in Qom, Iran, in 1403 AH. All surgeries will be performed by a skilled surgeon in a specialized surgical center. In order to control for confounding variables, patients will be standardized from the beginning of anesthesia to the administration of analgesics in the recovery room.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Age over 50 years • T-score -• 2.5 • BMI between 30-20 • Patient is free from uncontrolled chronic diseases such as diabetes or cardiovascular disorders. Exclusion criteria: • Previous surgery in the lumbar region • Degenerative disorders in other vertebrae • Use of opioids for pain relief • Unwillingness to follow up after surgery

Intervention groups
Group A includes patients who will undergo spinal fixation surgery with full reinforcement of pedicle screws with bone cement. Group B includes patients who will undergo spinal fixation surgery without cement reinforcement, and Group C includes patients whose surgical technique involves unilateral reinforcement of the caudal and cranial pedicle screws with bone cement and placement of the other screws without cement reinforcement.

Main outcome variables
Bleeding, pain, functional disability, infection, adjacent damage, intervertebral fusion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230222057496N6**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **prospective**

Last update: **2025-09-25, 1404/07/03**
Update count: **0**

Registration date
2025-09-25, 1404/07/03

Registrant information

Name
Parisa hajilo

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
2025-10-22, 1404/07/30

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of cranial and caudal pedicle screw-selective unilateral cemented versus fully reinforced pedicle screws in the lumbar spine of patients with osteoporosis a prospective randomized clinical trial.

Public title
Comparison of cranial and caudal pedicle screw-selective unilateral cemented versus fully reinforced pedicle screws in the lumbar spine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 50 years T-score < - 2.5 BMI between 30-20 The patient is free of uncontrolled chronic diseases such as diabetes or cardiovascular disorders.

Exclusion criteria:
Previous surgery in the lumbar region Degenerative disorders in other vertebrae Taking opioids to relieve pain Unwillingness to follow up after surgery

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be enrolled using a convenience sampling method and will be divided into three groups A, B, and C based on a randomized block design with rows of six. Group A includes patients who will undergo spinal fixation surgery with full reinforcement of pedicle screws with bone cement. Group B includes patients who will undergo spinal fixation surgery without cement reinforcement, and group C includes patients in whose surgical technique the caudal and cranial pedicle screws will be reinforced unilaterally with bone cement and the other screws will be placed without cement reinforcement.

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 Hamadan University of Medical Sciences

Street address
Hamedan, Shahid Fahmideh Blvd., Research Square, Central Headquarters of University of Medical Sciences, 5th Floor

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Approval date
2025-09-07, 1404/06/16

Ethics committee reference number
IR.UMSHA.REC.1404.449

Health conditions studied

1

Description of health condition studied
Degenerative disease of the lumbar spine

ICD-10 code
G32

ICD-10 code description
Other degenerative disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description
Bleeding

Timepoint
During surgery

Method of measurement
Blood, suction bottle and blood gases

2

Description
Time Surgery

Timepoint
During Surgery

Method of measurement
Smartwatch

3

Description
Pain

Timepoint
Before surgery and in the first month after surgery

Method of measurement

Visual analog scale

4

Description
infection
Timepoint
After surgery
Method of measurement
Southampton Scale

5

Description
Functional Disability
Timepoint
Before surgery and in the first month after surgery
Method of measurement
Functional Disability Questionnaire

Secondary outcomes

1

Description
Pain
Timepoint
12th month after surgery
Method of measurement
Visual analog scale

2

Description
Functional Disability
Timepoint
12th month after surgery
Method of measurement
Functional Disability Questionnaire

3

Description
Futon
Timepoint
12th month after surgery
Method of measurement
Radiographic image

4

Description
Loosening of the screw
Timepoint
12th month after surgery
Method of measurement
Radiographic image

5

Description
Adjacent segment damage
Timepoint
12th month after surgery
Method of measurement
Radiographic image

Intervention groups

1

Description
Intervention group: Pedicle Screw Fixation + Cement: Initially, a midline incision was made in the posterior region, and then a decompression procedure including bilateral partial facetectomy was performed for all patients. Before screw placement, two entry holes were made in the vertebral pedicles at the L3-L5 level using an awl, and then a 3-mm guide hole was created with a Lenke probe. The selected screws had a solid core and were made of titanium alloy. Fluoroscopic radiography using a C-arm was used to determine the exact placement of the screws. In the created hole, 2 ml of bone cement with special fillers was injected into each screw (all screws were inserted with cement reinforcement). In the next step, screws with a length of 40 to 50 mm and an outer diameter of 6 to 6.5 mm were placed precisely according to the method described by Weinstein et al. (17).
Category
Treatment - Surgery

2

Description
Intervention group: Pedicle Screw Fixation - Cement: Initially, a posterior incision was made for all patients, followed by decompression including bilateral partial facetectomy. Then, pedicle screws with a length of 40 to 50 mm and an external diameter of 6 to 6.5 mm were placed bilaterally at the L3-L5 level in the designated areas under fluoroscopic guidance. This process was performed without injecting cement into the bilateral guide holes. In the final stage, the screws were connected to each other using a 5.5 mm diameter rod, and the fixation process was fully completed by adjusting the vertebrae.
Category
Treatment - Surgery

3

Description
Intervention group: Pedicle Screw Fixation ± Cement: According to the previous surgical technique, after partial facetectomy, 2 ml of high-viscosity cement was unilaterally injected into the created cavity of the upper and lower screws along with bone fillers. In the next step, screws with a length of 40 to 50 mm and an outer diameter of 6 to 6.5 mm were precisely placed. The other screws were inserted without cement reinforcement. Finally, the rods and nuts were properly assembled and the structure was stabilized. The cement around the nuts was evaluated by CT scan within 72 hours after surgery and was evaluated according to the

classification of Yeom et al.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital, Qom

Full name of responsible person
Dr. Ali Mehrafshan

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Sponsors / Funding sources

1

Sponsor

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Grant name
Vice President for Research and Technology, Hamadan University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Hamedan 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
Ghoum University of Medical Sciences

Full name of responsible person
Ali Mehrafshan

Position
Neurosurgeon

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

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Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Information from all participants without personal information will be published in the form of tables as a general conclusion.

When the data will become available and for how long
After the sampling is completed and the final data analysis is performed

To whom data/document is available
General public

Under which criteria data/document could be used
In order to increase public awareness of unilateral and bilateral surgical methods, and improve the clinical skills of surgeons in choosing the most effective surgical method.

From where data/document is obtainable
Trusted databases

What processes are involved for a request to access data/document
Visit the desired database and use keywords to access the article.

Comments