# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

**Country**
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

**City**
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**Province**
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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**

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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 scientific inquiries

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## Person responsible for updating data

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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**