

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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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+98 25 3861 9252

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parisahajilo73@gmail.com

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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Postal code

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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

Fusion

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

Name of organization / entity

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Full name of responsible person

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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

Ghous 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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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Parisa Hajilo

Position

Faculty member

Latest degree

Master

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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