

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of clinical and radiological outcomes between two methods of using cortical screws and pedicle screws in multilevel lumbar spine fusion surgery at Imam Khomeini Hospital, Tehran

Protocol summary

Study aim

Overall objective: To compare clinical (VAS, ODI) and radiological outcomes (fusion rate, screw loosening, facet joint damage) between the two methods of using cortical screws (CBT) and pedicle screws (PS) in multilevel lumbar spine fusion surgery

Design

A controlled clinical trial with parallel groups, single-blind, randomized, on 102 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study will be a prospective, randomized clinical trial that will be conducted in the Neurosurgery Department of Imam Khomeini Hospital, Tehran, in 2025-2026. Diagnosis will be based on lumbar spine radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) in conjunction with clinical symptoms and physical examinations. Patients will be followed up for one year after surgery.

Participants/Inclusion and exclusion criteria

Patients from the Neurosurgery Department of Imam Khomeini Hospital, Tehran with the following inclusion criteria: Inclusion criteria: Male and female patients 18 years of age and older, patients with lumbar disease who are candidates for two- to four-level fusion surgery and have not responded to treatment for 3 months; Exclusion criteria: Patients with osteoporosis, patients with involvement of less than two levels of the lumbar spine or more than four levels, history of lumbar fusion surgery.

Intervention groups

All surgeries will be performed using the same surgical technique. It will be performed through a posterior midline incision. In the CBT group, a bilateral screw-rod system with cortical track screws will be used under fluoroscopic guidance. In the PS group, a bilateral screw-rod system with conventional pedicle screws will be

used.

Main outcome variables

Radiographic outcomes included facet joint damage (FJV) rate, screw placement accuracy, fusion rate, and screw loosening.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251010067572N1**

Registration date: **2025-11-05, 1404/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2025-11-05, 1404/08/14**

Update count: **0**

Registration date

2025-11-05, 1404/08/14

Registrant information

Name

mohammad doustkani

Name of organization / entity

Country

Iran (Islamic Republic of)

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mohammad.doustkani@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-09-29, 1404/07/07

Expected recruitment end date

2026-09-29, 1405/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical and radiological outcomes between two methods of using cortical screws and pedicle screws in multilevel lumbar spine fusion surgery at Imam Khomeini Hospital, Tehran

Public title

Comparison of clinical and radiological outcomes between two methods of using cortical screws and pedicle screws in multilevel lumbar spine fusion surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female patients 18 years of age and older
Patients with low back disease who are candidates for two- to four-level fusion surgery and whose symptoms include radiculopathy and/or nerve palsy, with or without back pain. Patients who have not responded to conservative treatment (medication and physical therapy) for at least 3 months or who have shown progressive neurological symptoms during this treatment. Patients who are willing to sign a research consent and follow-up for at least 1 year.

Exclusion criteria:

Patients with a T-Score greater than -2.5 in BMD (osteoporosis)
Patients with involvement of less than two lumbar spine levels or more than four levels
History of lumbar fusion surgery or active local/systemic infection or fracture
Pregnant patients
Inability to adhere to the 1-year follow-up schedule
Use of glucocorticoids or immunosuppressive drugs
Spondylolisthesis with Myroding grade $\geq$ III or IV

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **102****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be assessed for eligibility and, after obtaining written informed consent and basic information, will be randomly assigned to either Group A (PS screw) or Group B (CS screw). The patient will be blinded to the group assignment, but the surgeon and the medical staff will not be blinded; therefore, the study will be considered a single-blind study. Randomization will be performed using a block randomization approach.

A detailed, step-by-step procedure for performing block randomization for a clinical trial with 102 patients in two groups of 51 is presented: Objective: To randomly assign 102 patients to two equal groups (CBT screw group and pedicle screw group) in such a way that a relative balance between the number of participants in each group is maintained at each stage of patient recruitment.

1. Design specifications Total number of participants:

102 Number of groups: 2 groups (CBT and Pedicle)

Allocation ratio: 1:1 Randomization method: Block

randomization with variable block size 2. Block size selection To maintain balance while avoiding prediction

of allocation, variable block sizes (e.g., 4 and 6) are

used: Block 4: includes 2 people in the CBT group and 2

people in the Pedicle group Block 6: includes 3 people in

the CBT group and 3 people in the Pedicle group Number

of blocks required: Assuming a combination of blocks 4

and 6, to reach 102 people, the total block size must be

102 (12 blocks of 6 people and 3 blocks of 4 people =

102). 3. Generation of random allocation sequences

Using the site

<https://www.sealedenvelope.com/simple-randomiser/v1/lis>

sts and Excel, the output of the following steps will be

performed: For each block, all possible combinations of

symmetric allocation (CBT-Pedicle-CBT-Pedicle) are

listed. Using the RAND function in Excel, a random

selection is made from these combinations. This is

repeated until the total number of subjects is 102. 4.

Allocation Concealment The results of the generated

random sequence are placed in numbered and sealed

envelopes. Each envelope contains a sheet with the

name of the allocation group. Only the researcher

responsible for allocation (and preferably not involved in

the outcome assessment) opens the envelope when the

patient enters the study. 5. Allocation Implementation

After confirming the inclusion criteria and obtaining

informed consent from the patient, the patient is

allocated to one of the two groups based on the

envelope number (e.g., in order of arrival). The patient's

name, envelope number, and allocation group are

entered in the data recording form. 6. Practical example

for a block of 4: The same logic is followed for

subsequent blocks. To reduce bias in outcome

measurement, a consultant radiologist and a consultant

neurosurgeon will independently review the radiographs

and CT scans of each patient, and disagreements will be

resolved by discussion.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is blinded to the group allocation, but the surgeon and the treatment staff are not; therefore, the study is considered single-blind. The randomly generated sequence is placed in numbered, sealed envelopes. Each envelope contains a slip of paper with the name of the allocation group. Only the investigator responsible for allocation (and preferably not involved in the outcome assessment) opens the envelope when the patient enters the study.

Placebo

Not used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

End of keshavarz boulevard, doctor gharib street, imam Khomeini hospital complex

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

1995-09-19, 1374/06/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1404.285

Health conditions studied

1

Description of health condition studied

Multilevel lumbar spine fusion surgery

ICD-10 code

M48.0

ICD-10 code description

Spinal stenosis

Primary outcomes

1

Description

The patient's degree of functional disability in daily activities

Timepoint

At intervals before surgery/at discharge/one month after surgery/three months after surgery/one year after surgery

Method of measurement

ODI questionnaire

Secondary outcomes

1

Description

Facet joint injury rate

Timepoint

After surgery
Method of measurement
CT scan

2

Description

Screw placement accuracy

Timepoint

After surgery

Method of measurement

CT scan

3

Description

Fusion rate

Timepoint

At three and twelve months after surgery

Method of measurement

Ct scan

4

Description

Loosening of screws

Timepoint

At three and twelve months after surgery

Method of measurement

Ct scan

Intervention groups

1

Description

Intervention group: In the pedicle screws group, the entry site will be at the apex of the herringbone crest and the junction of the transverse process with the lateral edge of the superior articular process. An initial hole will be made using an awl and then advanced into the pedicle canal with the help of a pedicle probe, and finally a 40 mm deep hole will be made at an angle of 10-15 degrees to the superior vertebral plane. The entry site and drill path will be determined with C-arm guidance. After confirming the depth of the hole with a ball-tipped probe, screws of 40-45 mm in length and 6.0 mm in diameter will be inserted.

Category

Treatment - Surgery

2

Description

Control group: In the Cortical screws group, the screw insertion site will be midway between the superior articular process and 1-2 mm below the inferior border of the transverse process. The screw path will be from 5 o'clock to 11 or 12 o'clock on the left side, and from 7 o'clock to 12 or 1 o'clock on the right side. The screw tip will be positioned 1/3 to 1/2 posterior to the superior face of the vertebra. The insertion path will be determined with C-arm guidance. First, a 2-mm burr hole will be

created in the cortex of the isthmus to reduce the risk of isthmic fracture, then a primary hole will be created with a 2.5-mm drill to a depth of 30 mm. After confirming the path with a ball-tipped probe, a T-handle instrument will be inserted into the hole. Screws 35-40 mm long and 5.5 mm in diameter will be inserted for fusion.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Tehran

Full name of responsible person

Mohammad Doustkani

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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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Email

vcr@tums.ac.ir

Grant name

1690140000 Rials

Grant code / Reference number

92221

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Doustkani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A thesis and an article of the results of statistical analysis
and its discussion

When the data will become available and for how long

After defending the thesis and publishing the article

To whom data/document is available

Everyone

Under which criteria data/document could be used

For use in articles

From where data/document is obtainable

To the Tehran Medical Sciences Research Associate
website after registering the thesis or the journal in
which it is published.

What processes are involved for a request to access data/document

To the Tehran Medical Sciences Research Associate
website after registering the thesis or the journal in
which it is published.

Comments