Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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 ≥ III or IV
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target 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/lists 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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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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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