

# 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)

##### Phone

+98 21 6119 5920

##### Email address

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

**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/lits> 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 5920

**Email**

mohammad.doustkani@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Ramin Kordi

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6658 1560

**Fax**

+98 21 6693 8885

**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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**Postal code**

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**Fax****Email**

mohammad.doustkani@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Doustkani

**Position**

Resident

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Medical doctor

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**Fax****Email**

mohammad.doustkani@gmail.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Doustkani

**Position**

Resident

**Latest degree**

Medical doctor

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mohammad.doustkani@gmail.com

**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**