Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of pedicle screw fixation with cement augmentation versus without in the treatment of spinal stenosis following posterior spinal fusion surgery, superiority according to bone mineral density: A three-arm randomized open clinical trial

Protocol summary

Study aim
Evaluation of the effectiveness of pedicle screw fixation with and without cement on clinical and radiological outcomes in osteoporotic patients, as well as determine whether cement augmentation performance can be comparable to regular bone density.

Design
A three-arm parallel randomized interventional trial without blinding, but with a control group and a sample size of 92 patients with a one-year follow-up of patients.

Settings and conduct
The present study will conduct on 92 patients in Shohada Tajrish Hospital. patients will be stratified into intervention groups (T-score ≤ -1.5) and a control group (T-score > -1.5). Afterward, the osteoporotic group will be randomized into: Group II-A = osteoporosis without cement augmentation or Group II-B =osteoporosis+ cement augmentation. The intervention will be performed by a senior spine surgeon.

Participants/Inclusion and exclusion criteria
Patients >= 40 with spinal canal stenosis who are candidates for posterior spinal fusion surgery via pedicle screws fixation. Absence of other vertebral disorders such as tumors or infections- Absence of serious medical problems, such as congestive heart failure and cirrhosis, calcium absorption disorder, hyperparathyroid disease- Absence of spine abnormalities, including sagittal and coronal deformities.

Intervention groups
Intervention group 1)patients with T-score ≤ -1.5 and spinal canal stenosis who will undergo pedicle screw fixation without cement augmentation. Intervention group 2)patients with T-score ≤ -1.5 and spinal canal stenosis who will undergo pedicle screw fixation with cement augmentation. Control group: patients with T-score > -1.5 and spinal canal stenosis who will undergo pedicle screw fixation without cement augmentation.

Main outcome variables
Evaluation of changes in VAS score and radiological parameters before and after one year of surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190126042496N2**
Registration date: **2023-01-19, 1401/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-19, 1401/10/29**
Update count: **0**

Registration date
2023-01-19, 1401/10/29

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-18, 1401/10/28

Expected recruitment end date

2024-01-18, 1402/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of pedicle screw fixation with cement augmentation versus without in the treatment of spinal stenosis following posterior spinal fusion surgery, superiority according to bone mineral density: A three-arm randomized open clinical trial

Public title

pedicle screw fixation with cement augmentation versus without in the treatment of spinal stenosis following posterior spinal fusion surgery, superiority according to bone mineral density: A three-arm randomized open clinical trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

diagnosed with spinal stenosis by symptoms, signs, and imaging examinations advised for PSF surgery through pedicle screw fixation older than 40 years old

Exclusion criteria:

diagnosed with other vertebral disorders such as tumors or infections serious medical problems such as congestive heart failure and cirrhosis, calcium absorption disorder, hyperparathyroid disease diagnosed with spinal deformities including sagittal plane deformity and coronal imbalance

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Informed consent will be obtained from each participant before patient enrolment in the study. Patients who meet all the inclusion criteria and none of the exclusion criteria will be consecutively included and stratified into two groups according to T-score: Group I= non-osteoporotic (T-score >-1.5) and Group II= osteoporotic (T-score ≤-1.5). Afterward, the osteoporotic group will be randomized into one of the following study arms by the statistician according to a random allocation sequence by a random number table: Group II-A = osteoporosis without cement augmentation or Group II-B =osteoporosis+ cement augmentation. The intervention will be communicated to the patient by a surgeon.

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

Institutional Research Ethics Committee - Shahid Beheshti University of Medical Sciences

Street address

3rth floor, Faculty of Medicine, next to Taleghani Hospital, Evin, Shahid Chamran Highway

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Province

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Postal code

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Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.SBMU.MSP.REC.1401.086

Health conditions studied

1

Description of health condition studied

Patients with spinal canal stenosis are candidates for posterior spinal fusion surgery

ICD-10 code

M48.0

ICD-10 code description

Spinal stenosis

2

Description of health condition studied

Osteoporosis is defined as a mean adjusted T-score of -1.5 or below

ICD-10 code

M81

ICD-10 code description

Osteoporosis without current pathological fracture

Primary outcomes

1

Description

Changes in VAS score before and after posterior spinal

fusion surgery

Timepoint

The VAS score will be measured before and after one year of surgery to determine the degree of pain reduction.

Method of measurement

The patient's pain level is assessed on a horizontal line of 100 mm that its left end represents no pain, and the right end corresponds to the most severe pain that can be experienced. The patient is asked to mark the pain intensity they are experiencing currently.

Secondary outcomes

1

Description

Proximal junctional kyphosis (PJK): A rise of over 20° in the Cobbs' angle between the lower endplate of the upper instrumented vertebra (UIV) and the upper endplates of two super-adjacent vertebrae between the immediate postoperative and after one year follow-up

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Through upright lateral radiographs

2

Description

Proximal junctional vertebral fracture (PJVF): The fracture of UIV or UIV +1

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Anteroposterior and lateral plain radiographs, and computed tomography (CT)

3

Description

Adjacent segment disease (ASD):Degeneration of the mobile spinal segments above or below a fused spinal segment

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Anteroposterior and lateral plain radiographs, and computed tomography (CT)

4

Description

Screw fracture: Fracture of rod following pedicle screw fixation surgery

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Anteroposterior and lateral plain radiographs, and computed tomography (CT)

5

Description

Rod fracture: Fracture of rod following pedicle screw fixation surgery

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Anteroposterior and lateral plain radiographs, and computed tomography (CT)

6

Description

Screw loosening: The appearance of a radiolucent rim >1 mm (a halo) around at least one screw on radiography or CT scan

Timepoint

Immediately after surgery and after one year follow-up

Method of measurement

Anteroposterior and lateral plain radiographs, and computed tomography (CT)

Intervention groups

1

Description

Intervention group: (Group II-A) A group of osteoporotic patients with T-score ≤ -1.5 and spinal canal stenosis who will undergo pedicle screw fixation without cement augmentation.

Category

Treatment - Surgery

2

Description

Intervention group: (Group II-B) A group of osteoporotic patients with T-score ≤ -1.5 and spinal canal stenosis who will undergo pedicle screw fixation with cement augmentation (0.8-1 cc of polymethylmethacrylate (PMMA) per screw, bilaterally into each vertebra with a viscosity slightly thinner than toothpaste. The screw is implanted into the vertebra prior to the complete solidification of the cement, and the rod is attached following solidification.)

Category

Treatment - Surgery

3

Description

Control group: A group of non-osteoporotic patients with T-score > -1.5 and spinal canal stenosis who will undergo pedicle screw fixation without cement augmentation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada-e-Tajrish hospital

Full name of responsible person
Mohammadreza Shahmohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Neurofunctional Research Center of Shohada Tajrish Hospital

Full name of responsible person
Prof. Dr. Afshin Zarghi

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Grant name

Grant code / Reference number

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

Title of funding source
Neurofunctional Research Center of Shohada Tajrish Hospital

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammadreza Shahmohammadi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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