

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 \leq -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 \geq 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 \leq -1.5 and spinal canal stenosis who will undergo pedicle screw fixation without cement augmentation. Intervention group 2)patients with T-score \leq -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

Name

Mohammadrez Shahmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Street address

Shohada Tajrish Hospital, Tajrish Square, Tehran, Iran

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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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neurofunctional.cntr@gmail.com

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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Position

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Specialist

Other areas of specialty/work

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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