Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the treatment outcomes of laminectomy alone, laminectomy with arthrodesis and laminectomy with posterior fusion in degenerative lumbar spinal canal stenosis patients

Protocol summary

Study aim

To compare the clinical and radiological outcomes of laminectomy alone, laminectomy with non instrumented arthrodesis, and laminectomy with instrumented posterior fusion in patients with degenerative lumbar spinal stenosis.

Design

Randomized controlled, three arm, parallel group clinical trial including 120 patients. Participants were randomly allocated equally to three treatment groups. Recruitment was completed over a three month period.

Settings and conduct

The trial was conducted at Imam Khomeini Hospital, Urmia, Iran. Eligible patients were enrolled after informed consent. Clinical and radiological assessments were performed before surgery and during follow up at three months, nine months, and the final visit.

Participants/Inclusion and exclusion criteria

Adults with symptomatic multilevel degenerative lumbar spinal stenosis and persistent low back or leg pain despite at least six months of conservative treatment. Exclusion criteria: previous surgery at the same level, active infection, spinal instability, severe degenerative scoliosis, or sagittal imbalance.

Intervention groups

Group 1, laminectomy alone; Group 2, laminectomy with non instrumented arthrodesis; Group 3, laminectomy with instrumented posterior fusion using pedicle screw fixation. Standard perioperative care will be identical in all groups.

Main outcome variables

Low back pain; leg pain; lumbar lordosis; distal lumbar lordosis; proximal segmental lordosis; proximal junctional kyphosis; patient satisfaction after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251203068207N1**
Registration date: **2026-07-25, 1405/05/03**
Registration timing: **prospective**

Last update: **2026-07-25, 1405/05/03**
Update count: **0**

Registration date

2026-07-25, 1405/05/03

Registrant information

Name

Saeed Pourmoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3224 6858

Email address

school.saeed@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-26, 1405/05/04

Expected recruitment end date

2026-09-20, 1405/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the treatment outcomes of laminectomy alone, laminectomy with arthrodesis and laminectomy with posterior fusion in degenerative lumbar spinal canal stenosis patients

Public title
Comparison of outcomes of surgical interventions in patients with degenerative lumbar spinal stenosis

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of degenerative lumbar spinal stenosis confirmed by MRI Presence of neurogenic claudication and/or radicular leg pain Failure of conservative treatment for at least 6 months Candidate for lumbar decompression surgery Ability to complete follow-up assessments up to 12 months Written informed consent obtained No evidence of overt lumbar spinal instability Age between 18 and 80 years

Exclusion criteria:
Meyerding grade II or higher spondylolisthesis . Anteroposterior translation greater than 3 mm on flexion-extension radiographs Dynamic angular motion greater than 10 degrees Previous lumbar surgery at the affected level Spinal tumor, infection, or traumatic fracture Cauda equina syndrome or progressive neurological deficit Severe scoliosis or significant spinal deformity Severe systemic disease contraindicating surgery Refusal to participate in the study Inability to complete postoperative follow-up

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants who provided written informed consent were randomly assigned to one of three study groups using block randomization with a 1:1:1 allocation ratio. The random allocation sequence was generated by computer software, and participants were assigned according to randomly permuted blocks to ensure balanced group sizes throughout the study. The three study arms consisted of: (1) decompressive laminectomy alone, (2) laminectomy with non-instrumented arthrodesis, and (3) laminectomy with instrumented posterior fusion.

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
Research Ethics Committees of Urmia University of Medical Sciences – Imam Khomeini University Hospit

Street address
South Khayyam Street, before Jihad Square, Alley 27, Apartment 27, Unit 7

City
URMIA

Province
West Azarbaijan

Postal code
5714614476

Approval date
2024-05-29, 1403/03/09

Ethics committee reference number
IR.UMSU.HIMAM.REC.1403.027

Health conditions studied

1

Description of health condition studied
Degenerative Lumbar Spinal Stenosis

ICD-10 code
M48.06

ICD-10 code description
Spinal stenosis, lumbar region

Primary outcomes

1

Description
Severity of low back pain

Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit

Method of measurement
Low back pain severity will be measured using the Visual Analogue Scale for pain

2

Description
Severity of leg pain

Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit

Method of measurement
Severity of leg pain will be measured using the Visual Analogue Scale for pain.

3

Description
Lumbar lordosis
Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit
Method of measurement
Lumbar lordosis will be measured on standing lateral lumbar spine radiographs.

4

Description
Distal lumbar lordosis
Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit
Method of measurement
Distal lumbar lordosis will be measured on standing lateral lumbar spine radiographs.

5

Description
Proximal segmental lordosis
Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit
Method of measurement
Proximal segmental lordosis will be measured on standing lateral lumbar spine radiographs.

6

Description
Proximal junctional kyphosis
Timepoint
Before surgery, three months after surgery, nine months after surgery, and at the final postoperative follow up visit
Method of measurement
Proximal junctional kyphosis will be measured on standing lateral spinal radiographs.

7

Description
Patient satisfaction after surgery
Timepoint
At the final postoperative follow up visit
Method of measurement
Patient satisfaction will be assessed using a standardized patient satisfaction questionnaire.

Secondary outcomes

1

Description
Postoperative complications
Timepoint
During hospital stay, three months after surgery, nine months after surgery, and at the final follow up visit
Method of measurement
Postoperative complications will be assessed by clinical examination, medical records, and radiological findings.

2

Description
Length of hospital stay
Timepoint
From hospital admission until discharge
Method of measurement
Length of hospital stay will be calculated from hospital medical records.

3

Description
Need for reoperation
Timepoint
Until the final postoperative follow up visit
Method of measurement
Need for reoperation will be determined from medical records.

Intervention groups

1

Description
Intervention group: Intervention Group 1: Patients will undergo decompressive laminectomy followed by non instrumented arthrodesis. The procedure will be performed by experienced spine surgeons according to the institutional standard protocol. Perioperative care will be identical for all participants.
Category
Treatment - Surgery

2

Description
Intervention group: Intervention Group 2: Patients will undergo decompressive laminectomy followed by instrumented posterior fusion using pedicle screw fixation. All procedures will be performed according to the institutional standard protocol by experienced spine surgeons. Perioperative care will be identical in all groups.
Category
Treatment - Surgery

3

Description
Control group: Control Group: Patients will undergo decompressive laminectomy alone without arthrodesis or instrumentation. Perioperative management and postoperative care will be identical to the other study groups.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Saeed Pourmoghadam
Street address
Imam Khomeini Hospital., Ershad Ave., Modarress Blvd
City
URMIA
Province
West Azarbaijan
Postal code
57157-89397
Phone
+98 44 3345 7286
Email
school.saeed128@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Hamdreza Khalili
Street address
Vice Chancellor for Research and Technology, Urmia University of Medical Sciences, End of Jihad Avenue, Urmia, West Azerbaijan, Iran
City
URMIA
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 1930
Email
research@umsu.ac.ir
Web page address
https://research.umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Saeed Pourmoghadam
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Shahid Chmran Dormitory ,Tarzi street , Imam khomeini street
City
Urmia
Province
West Azarbaijan
Postal code
5718748983
Phone
+98 44 3224 6858
Fax
Email
School.saeed@outlook.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saeed Pourmoghadam
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Shahid Chmran Dormitory ,Tarzi street , Imam khomeini street
City

Urmia

Province

West Azarbaijan

Postal code

5718748983

Phone

+98 44 3224 6858

Fax

Email

School.saeed@outlook.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saeed Pourmoghadam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Shahid Chmran Dormitory ,Tarzi street , Imam khomeini street

City

Urmieh

Province

West Azarbaijan

Postal code

5718748983

Phone

+98 44 3224 6858

Fax

Email

School.saeed@outlook.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information is available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis plan, clinical study report, and data dictionary will be available after publication of the study results. Individual participant data and informed consent forms will not be shared.

When the data will become available and for how long

From six months after publication of the study results until five years after publication.

To whom data/document is available

Academic researchers, faculty members, and graduate students affiliated with recognized academic or research institutions who submit a scientifically justified request.

Under which criteria data/document could be used

Documents may be used only for scientific research, systematic reviews, meta analyses, or secondary analyses after approval by the principal investigator and in compliance with confidentiality and research ethics requirements.

From where data/document is obtainable

Requests should be submitted to the principal investigator or the Research Vice Chancellor of Urmia University of Medical Sciences through the official email address.

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

Written requests will be reviewed by the principal investigator. After research committee approval and confirmation of ethical requirements, the requested documents will be provided within four weeks.

Comments

No further information is available.