

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Pourmoghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3224 6858

Email address

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Recruitment status

recruiting

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 Pourmoghdam

Street address

Imam Khomeini Hospital., Ershad Ave., Modarress Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamdreza Khalili

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Vice Chancellor for Research and Technology, Urmia University of Medical Sciences, End of Jihad Avenue, Urmia, West Azerbaijan, Iran

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Web page address

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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

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 Pourmoghdam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Position

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Latest degree

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Person responsible for updating data

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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.