Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical and biomechanical comparison of microscopic bilateral laminotomy versus total laminectomy with posterior spinal fusion for decompression of central canal and lateral recess simultaneous stenosis, with a focus on multilevel stenosis: A prospective comparative study.

Protocol summary

Study aim
To compare the clinical and biomechanical outcomes of microscopic bilateral laminotomy versus total laminectomy+ PSF in treating multi-level lumbar spinal stenosis (LSS)

Design
A two-arm parallel randomized interventional trial without blinding, with a sample size of 76 patients.

Settings and conduct
The present study will conduct on 76 patients in Shohada Tajrish Hospital. Patients will be randomized into intervention groups: A (Microscopic bilateral laminotomy) and B (Total laminectomy+ PSF).

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients between 30-75 with ≥ 3 levels LSS; stenosis of the central canal (mild to moderate), and lateral recess simultaneously, who suffers from resistant radicular pain as the primary complaint. Exclusion criteria: patients with severe stenosis of the central canal who suffer from severe neurogenic claudication that limits their ability; extruded discs or those requiring discectomy; osteoporotic patients T score < -1.5; previous history of laminotomy, laminectomy, or PSF 5.Serious medical conditions that preclude surgical procedures; current metabolic, rheumatologic, or inflammatory disorders requiring corticosteroid consumption; spinal deformity.

Intervention groups
Intervention group 1: patients with multi-level spinal stenosis, simultaneously stenosis of the central canal and lateral recess, who will be scheduled to undergo microscopic bilateral laminotomy. Intervention group 2: patients with multi-level spinal stenosis, simultaneously stenosis of the central canal and lateral recess, who will be scheduled to undergo total laminectomy with PSF (bilaterally removal of the lamina ≥ 3, spinous processes, interspinous intertransverse ligaments and partial medial facetectomy, as well as PSF)

Main outcome variables
Changes in Visual Analogue Scale and Pelvic incidence-lumbar lordosis mismatch

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190126042496N3**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

Registration date
2023-02-01, 1401/11/12

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-25, 1401/11/05

Expected recruitment end date
2023-07-27, 1402/05/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical and biomechanical comparison of microscopic bilateral laminotomy versus total laminectomy with posterior spinal fusion for decompression of central canal and lateral recess simultaneous stenosis, with a focus on multilevel stenosis: A prospective comparative study.

Public title
Clinical and biomechanical outcomes following decompression of central canal and lateral recess simultaneous stenosis, with a focus on multilevel stenosis: A randomized comparison of microscopic bilateral laminotomy versus total laminectomy with posterior spinal fusion.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Between 30- and 75-year-old age Multi-level canal stenosis (≥ 3 levels) Stenosis of both the central canal (mild to moderate) and the lateral recess simultaneously. Failure of conservative therapy for radicular pain after six months. Radicular pain predominates over claudication(mild).
Exclusion criteria:
Patients with severe stenosis of the central canal. Patients with severe neurogenic claudication suffer from leg pain that limits their ability to stand or walk. Extruded discs or those requiring discectomy Osteoporotic patients with a T score < -1.5 Previous spinal surgery history (laminotomy , laminectomy, or posterior spinal fusion) Serious medical conditions such as congestive heart failure, cirrhosis, and other chronic diseases that preclude surgical procedures. Even though patients develop cardiac, renal, or pulmonary disorders during the study, they will be excluded. Current metabolic or rheumatologic and inflammatory disorders requiring corticosteroid consumption. Spinal deformity
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
By using a random number table (simple randomization), all patients who meet all the inclusion and exclusion criteria will be consecutively recruited from outpatient clinics and randomized into one of the study arms by the statistician. (1:1)
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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Tehran
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Approval date
2021-01-26, 1399/11/07
Ethics committee reference number
IR.SBMU.MSP.REC.1399.655

Health conditions studied

1

Description of health condition studied
Patients with multilevel spinal canal stenosis, simultaneous stenosis of the central canal, and lateral recess.
ICD-10 code
M48.0
ICD-10 code description
Spinal stenosis

Primary outcomes

1

Description
VAS changes : Post-op versus pre-op VAS changes for leg pain and back pain
Timepoint
VAS scores will be measured before surgery, after 6-9 months, and after 18-24 months to determine the extent of pain relief.

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.

2

Description
Duration of hospitalization
Timepoint
Total number of hospital admission days
Method of measurement
Number of days staying in hospital with reference to medical records

3

Description
Duration of operation
Timepoint
During surgery
Method of measurement
The number of hours it takes for the operation to be completed.

4

Description
Blood transfusion: The number of patients requiring blood transfusions.
Timepoint
During surgery
Method of measurement
Based on doctor's diagnosis.

5

Description
Wound infection and discharge: Incidence of postoperative wound infection and discharge
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis.

6

Description
Incidental durotomy: An accidental puncture or laceration of dura during a procedure.
Timepoint
During surgery
Method of measurement
Based on doctor's diagnosis.

7

Description
meningitis: Incidence of meningitis after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis.

8

Description
Revision surgery: The number of patients requiring revision surgery either due to technical issues or infections.
Timepoint
Immediately after surgery until the end of the follow-up time
Method of measurement
Based on doctor's diagnosis.

9

Description
Root injury: Incidence of root injury during surgery
Timepoint
During surgery
Method of measurement
Based on doctor's diagnosis.

10

Description
Vacuum sign: Incidence of a collection of gas in the intervertebral disc space
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
Based on doctor's diagnosis via lateral plain radiographs.

11

Description
Adjacent segment disease (ASD): Degeneration of the mobile spinal segments between upper instrumented vertebra (UIV) and UIV+2 leading to spinal canal stenosis or discopathy .
Timepoint
After 18-24 months follow-up
Method of measurement
Anteroposterior and lateral plain radiographs, and computed tomography (CT)

12

Description
Hypermobility: Increased range of motion between UIV and UIV+2
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
Flexion-extension radiographs.

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 follow-up time
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral radiograph

2

Description
Sagittal vertical axis (SVA): The length of a horizontal line connecting the superior-posterior endplate of S1 to a vertical plumb line that drawn from the mid-point of the C7 vertebral body. This horizontal distance should be located within ± 5mm of the superior-posterior endplate of S1.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral spine radiographs

3

Description
Pelvic incidence (PI): The angle is formed by the perpendicular line running from the midpoint of the sacral plate and a line connecting that point to the center of the bicoxofemoral axis that serves as the foundation for all other spinal curves.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral radiograph

4

Description
Pelvic tilt (PT): The angle between the vertical axis and the line connecting the center of the coxofemoral axis to the midpoint of the S1 endplate.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral radiograph

5

Description
Sacral slope (SS): The angle between the horizontal reference line and the line parallel to the superior plate of S1.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral radiograph

6

Description
lumbar lordosis (LL): The angle between the caudal endplate of L5 and the upper plane of the L1 lumbar vertebra.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The standing lateral radiograph

7

Description
Pelvic incidence-lumbar lordosis mismatch (DPILL = PI-LL): A mismatch between pelvic incidence and lumbar lordosis strongly correlates with the sagittal balance and has become a key element in treating adult deformities.
Timepoint
Immediately after surgery, after 6-9 months, and after 18-24 months follow-up
Method of measurement
The difference between pelvic incidence and lumbar lordosis

Intervention groups

1

Description
Intervention group 1(Group A): A group of patients with multi-level spinal canal stenosis, simultaneously stenosis of the central canal and lateral recess, who will be scheduled to undergo lumbar decompression surgery via microscopic bilateral laminotomy through a unilateral approach.
Category
Treatment - Surgery

2

Description
Intervention group 2 (Group B): A group of patients with multi-level spinal canal stenosis, simultaneously stenosis of the central canal and lateral recess, who will be scheduled to undergo lumbar decompression surgery via total laminectomy and partial medial facetectomy with posterior spinal fusion (bilaterally removal of the bony lamina ≥ 3 lamina, spinous processes, and interspinous intertransverse ligaments and medial facet, as well as posterior spinal fusion with pedicle screw fixation to prevent instability)
Category
Treatment - Surgery

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
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Full name of responsible person
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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
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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