Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the clinical outcomes of posterior longitudinal ligament resection with preservation in patients candidates for anterior cervical disc surgeries

Protocol summary

Study aim
To determine and compare the clinical outcomes and complications of posterior longitudinal ligament resection versus preservation in patients undergoing anterior cervical disc surgery

Design
This is a Phase 3, randomized, single-blind, controlled, parallel-group clinical trial that will be conducted on 60 patients. Randomization will be performed using the block randomization method via 'Random Allocation' software.

Settings and conduct
This study will be conducted on patients admitted to Urmia Imam Khomeini Hospital. Patients will be assigned to one of two groups—either undergoing resection or preservation of the posterior longitudinal ligament—and clinical outcomes will be compared between two groups. The study is single-blinded, meaning patients will be unaware of their group assignment.

Participants/Inclusion and exclusion criteria
This study will be conducted on patients who candidates for anterior cervical disc surgery with cervical disc disease confirmed by MRI and , and who present with associated neurological symptoms (such as neck and arm pain, muscle weakness, or sensory loss). Key exclusion criteria include cervical myelopathy, ossification of the posterior longitudinal ligament (OPLL), trauma patients, the need for 360-degree cervical surgery, a history of prior cervical surgery, severe systemic diseases, active infection, and severe spinal pathologies.

Intervention groups
In intervention group, microscopic anterior cervical discectomy and fusion with resection (opening) of the posterior longitudinal ligament after disc removal will be done. In control group, microscopic anterior cervical discectomy and fusion with preservation of the intact posterior longitudinal ligament will be done.

Main outcome variables
Neck disability; Neck pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230520058233N4**
Registration date: **2026-11-09, 1405/08/18**
Registration timing: **prospective**

Last update: **2026-11-09, 1405/08/18**
Update count: **0**

Registration date
2026-11-09, 1405/08/18

Registrant information

Name
Peyman Gholipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2027-02-19, 1405/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the clinical outcomes of posterior longitudinal ligament resection with preservation in patients candidates for anterior cervical disc surgeries

Public title
Comparing the posterior longitudinal ligament resection with preservation in cervical disc surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for anterior cervical disc surgery with cervical disc disease confirmed by MRI and clinical examination Relevant neurological symptoms (neck and arm pain, muscle weakness or sensory loss) Failure of medical treatment
Exclusion criteria:
Cervical myelopathy Ossification of the posterior longitudinal ligament (OPLL) Trauma patients Need for 360-degree cervical surgery History of previous neck surgery Severe systemic disease Active infection Severe spinal disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated to the intervention (PLL resection) or control (PLL preservation) group using block randomization based on numbers generated by Random Allocation software. For 60 patients, 15 blocks of 4 will be used. The random sequence will be generated by a team member not involved in surgery or outcome assessment and kept in opaque, numbered, sealed envelopes. Each patient's envelope will be opened intraoperatively after disc removal.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient will be blinded to group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Imam Khomeini Hospital; Urmia University of Medical Sciences
Street address
Imam Khomeini hospital., Ershad Ave., Modarress Blvd.
City
Urmia
Province
West Azarbaijan
Postal code
5715789397
Approval date
2025-07-30, 1404/05/08
Ethics committee reference number
IR.UMSU.HIMAM.REC.1404.037

Health conditions studied

1

Description of health condition studied
Anterior cervical disc surgeries
ICD-10 code
M40.12
ICD-10 code description
Other secondary kyphosis, cervical region

Primary outcomes

1

Description
Neck disability
Timepoint
2 days, 2 weeks and 1 month after surgery
Method of measurement
Neck Disability Index (NDI)

2

Description
Neck pain
Timepoint
2 days, 2 weeks and 1 month after surgery
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Fusion

Timepoint

6 months after surgery

Method of measurement

CT scan

2

Description

Cage subsidence

Timepoint

6 months after surgery

Method of measurement

CT scan

3

Description

Postoperative complications (infection, DVT and embolism, recurrent laryngeal nerve injury, wound dehiscence)

Timepoint

One month after surgery

Method of measurement

Clinical examination

4

Description

Intraoperative blood loss

Timepoint

Intraoperative

Method of measurement

Suctioned blood volume (cc)

Intervention groups

1

Description

Intervention group: In this group, ئicroscopic anterior cervical discectomy and fusion with resection (opening) of the posterior longitudinal ligament after disc removal will be done.

Category

Treatment - Surgery

2

Description

Control group: In this group, microscopic anterior cervical discectomy and fusion with preservation of the intact posterior longitudinal ligament will be done.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

Dr. Peyman Gholipour

Street address

Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Khalkhali

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Urmia University of Medical Sciences., Resalat street., Jahad Blvd., Urmia, Iran.

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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
Dr. Peyman Gholipour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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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
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Questionnaires and Outcome Measurement Scales

When the data will become available and for how long
After the article is published

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Use in conducting research projects

From where data/document is obtainable
Corresponding author of the article

What processes are involved for a request to access data/document
Email: gholipour.p@umsu.ac.ir

Comments