Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison study of surgical methods of laminectomy with and without unilateral and bilateral lumbar pedicle screw fixation in young patients with spinal canal stenosis: a randomized clinical trial.

Protocol summary

Study aim

Comparison of laminectomy surgical methods with and without unilateral and bilateral lumbar pedicle screw fixation in young patients with spinal canal stenosis: a randomized clinical trial

Design

The clinical trial has 3 intervention groups. 81 patients are included in the study in parallel and without blinding. Random allocation is done based on permutation block design with 6 rows.

Settings and conduct

The surgery is performed by a surgeon at Valiasr Hospital in Qom province.

Participants/Inclusion and exclusion criteria

Patients with lumbar spine degeneration-Age range less than 40 years, observation of lumbar spinal stenosis in the L3-L5 range in magnetic imaging (a discopathy level at the level of L3-L4 or L4-L5 vertebrae), use of conservative treatments for at least 6 weeks, BMI between 20 30, visual analog scale above 7 before surgery, as well as the presence of any previous surgery in the lumbar region, anemia, rheumatoid arthritis, osteoporosis, hypertension and uncontrolled diabetes, or the presence of any active infection in the body, consumption Anticoagulant drugs or any type of drug effective on wound healing, long-term use of opioids, smoking and other narcotic drugs before surgery to reduce pain, the presence of any pathological or discopathy in other vertebrae, the presence of spondylolisthesis of any degree. In the beads, it is considered as the criteria of not entering the study.

Intervention groups

A: Laminectomy group without fixation B: Laminectomy group with unilateral fixation C: Laminectomy group with bilateral fixation

Main outcome variables

The variables investigated in this study include the clinical results (pain, quality of life, rehabilitation rate) of the patients, which are evaluated in the form of repeated measurements. Radiological results (fusion, disc recurrence, screw loosening) will also be evaluated 6 months after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057496N2**
Registration date: **2023-12-06, 1402/09/15**
Registration timing: **prospective**

Last update: **2023-12-06, 1402/09/15**
Update count: **0**

Registration date

2023-12-06, 1402/09/15

Registrant information

Name

Parisa hajilo

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-06-09, 1403/03/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison study of surgical methods of laminectomy with and without unilateral and bilateral lumbar pedicle screw fixation in young patients with spinal canal stenosis: a randomized clinical trial.

Public title
Comparison study of surgical methods of laminectomy with and without unilateral and bilateral lumbar pedicle screw fixation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range less than 40 years observation of lumbar spinal stenosis in the L3-L5 range in magnetic imaging (a discopathy level at the level of L3-L4 or L4-L5 vertebrae) use of conservative treatments for at least 6 weeks BMI between 20-30 visual analog scale above 7 before surgery
Exclusion criteria:
The presence of any previous surgery in the lumbar region Rheumatoid arthritis, osteoporosis, high blood pressure and uncontrolled diabetes, or the presence of any active infection in the body Taking anti-coagulant drugs or any type of drug effective on wound healing, long-term use of opioids, smoking and other narcotic drugs before surgery to reduce pain The presence of any pathological or discopathy material in other vertebrae
Age
To **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be included in the study as available sampling and will be randomly divided into three groups A, B, C based on permutation block design (rows of 6). Allocation concealment is done using a sealed envelope (the envelope contains letters) which will be opened in the operating room after the induction of the patient. The amount of electrocautery current voltage will be set the same in all patients.
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
Ethics Committee of Hamadan University of Medical Sciences
Street address
5th floor, Central Headquarters of University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan, Hamedan
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۴۸۷۳۶
Approval date
2023-11-29, 1402/09/08
Ethics committee reference number
IR.UMSHA.REC.1402.553

Health conditions studied

1

Description of health condition studied
Lumbar spine degenerative disease
ICD-10 code
G30-G32
ICD-10 code description
Other degenerative diseases of the nervous system

Primary outcomes

1

Description
Bleeding
Timepoint
during surgery
Method of measurement
Accumulated blood in the suction bottle and blood gases

2

Description
time of surgery
Timepoint
during surgery
Method of measurement
stopwatch

3

Description
Pain
Timepoint
During surgery and 6 months after surgery
Method of measurement
Visual Analogue Scale

4

Description
rehabilitation
Timepoint
Before surgery
Method of measurement
Oswestry Disability Index

5

Description
Quality of Life
Timepoint
Before surgery
Method of measurement
Varusherbon 36-item quality of life questionnaire

6

Description
Wound Healing
Timepoint
Up to one month after surgery
Method of measurement
Southampton Wound Healing Assessment Scale

Secondary outcomes

1

Description
rehabilitation
Timepoint
6 months after surgery
Method of measurement
Oswestry Disability Index

2

Description
Quality of Life
Timepoint
6 months after surgery
Method of measurement
Varusherbon 36-item quality of life questionnaire

3

Description
pain
Timepoint
3 and 6 months after surgery
Method of measurement
مقیاس آنالوگ بینایی

4

Description
fution
Timepoint
6 months after surgery
Method of measurement
Brantigan Steffee-Fraser scale

5

Description
Adjacent segment disease
Timepoint
6 months after surgery
Method of measurement
Prrmann grading system

6

Description
Spondylolisthesis
Timepoint
6 months after surgery
Method of measurement
meyerding classification

Intervention groups

1

Description
Intervention group: Laminectomy with unilateral fixation
Category
Treatment - Surgery

2

Description
Intervention group: Laminectomy with bilateral fixation
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Waliasr Hospital
Full name of responsible person
dr.ali mehrafshan
Street address
Tawheed square, alley 9
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قم
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Parisa hajilo
Position
Master's student in the operating room
Latest degree
Bachelor
Other areas of specialty/work
Others
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
The information of all participants without individual information will be published in the majority of tables as a general conclusion.

When the data will become available and for how long
After the end of the patient admission and the final analysis of the data

To whom data/document is available
The general public

Under which criteria data/document could be used
In order to increase people's awareness in the field of laminar ectone surgery with and without prosthesis, to improve the clinical skills of patients in the field of choosing a more effective surgical method according to the lifestyle and clinical condition of patients.

From where data/document is obtainable
Valid databases for publishing articles

What processes are involved for a request to access data/document
Refer to the desired database and use keywords to access the article

Comments