

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 of 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 end, 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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+98 25 3861 9252

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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

۶۵۱۷۸۳۸۷۳۶

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

fusion

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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Ghoush

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Behzad Imni
Street address
Research Square, Shahid Fahmideh Blvd., Central
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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 scientific inquiries

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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