

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative study of L4-L5-S1 vertebral fusion treatment results with L5-S1 in patients with high grade L5-S1 spondylolisthesis

Protocol summary

Study aim

Comparison of postoperative complications (infection, bleeding, pain) in L4-L5-S1 fixation surgery group in comparison with L5-S1 fixation surgery group

Design

This study was a clinical trial with parallel and non-blinding groups and 70 patients with spondylolisthesis were included in Excel program based on the file number and were divided into case and control groups based on the random button.

Settings and conduct

This study was performed in 2020 in Al-Zahra Educational and Medical Center of Isfahan by clinical trial without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: High grade L5-S1 spondylolisthesis
Candidate for vertebral fusion operation with instrumentation Slip on the surface of a Vertebrae
Patient consent to participate in the study Age less than 60 years
Exclusion criteria: Patients with neurological defects and in need of emergency surgery Patients with a history of underlying diabetes and neuropathy Patients with a history of heart disease and preoperative anticoagulant use Patients who smoke and are addicted to drugs and alcohol Patients with metabolic bone diseases

Intervention groups

In the intervention group, the vertebral fixation is placed on the surface of the L4-L5-S1 vertebrae using pedicle screws and with pedicular screws, and three lumbar vertebrae are fixed. In the control group, the device is placed in the vertebral body with pedicular screws on the surface of the L5-S1 vertebrae and two lumbar vertebrae are fixed.

Main outcome variables

Pain, reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201130049541N1**

Registration date: **2021-01-08, 1399/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-08, 1399/10/19**

Update count: **0**

Registration date

2021-01-08, 1399/10/19

Registrant information

Name

Ali Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 0666

Email address

alimokhtary2001@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of L4-L5-S1 vertebral fusion treatment results with L5-S1 in patients with high grade L5-S1 spondylolisthesis

Public title
Results of L4-L5-S1 vertebral fusion treatment with L5-S1 in patients with L5-S1 spondylolisthesis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
High grade L5-S1 spondylolisthesis Candidate for vertebral fusion operation with instrumentation Slip on the surface of a Vertebrae Patient consent to participate in the study Age less than 60 years
Exclusion criteria:
Patients with neurological defects and in need of emergency surgery Patients with a history of underlying diabetes and neuropathy Patients with a history of heart disease and preoperative anticoagulant use Patients who smoke and are addicted to drugs and alcohol Patients with metabolic bone diseases

Age
To **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random function of Excel software based on patient file number will be used for randomization. Patients with spondylolisthesis were included in the Excel program based on the file number and were divided into case and control groups based on the random button. In total, there were two groups of 35 people. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want 35 people in each group. As a result, sequences 1 to 2 should be repeated 35 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 35 for repeating the sequence. In this way, 70 units will be produced.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.MUI.MED.REC.1398.181

Health conditions studied

1

Description of health condition studied

Spondylolisthesis

ICD-10 code

M43.1

ICD-10 code description

Spondylolisthesis

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before, one month, three months and six months after surgery

Method of measurement

Using the visual pain scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

The work of vertebral fixation in the first group using the device method in the vertebral body using pedicular screws is located on the surface of the vertebrae L4-L5-S1 and in fact, in this group three vertebrae are fixed . (L4-L5-S1 fixation surgery using pedicular screws with L5-S1 interbody fusion with autologous bone graft)

Category

Treatment - Surgery

2

Description

Control group: The device is placed in the vertebral body using pedicular screws on the surface of L5-S1 vertebrae and two lumbar vertebrae are fixed (L5-S1 fixation surgery using pedicular screws with L5-S1 interbody fusion With autologous bone graft)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Educational and Medical Center

Full name of responsible person

Majid Rezvani

Street address

Al-Zahra Educational and Medical Center, Sofeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou Javanmardi

Street address

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alzahra@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Majid Rezvani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Majid Rezvani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mokhtari

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Al-Zahra Educational and Medical Center, Sofeh
Boulevard

City

Isfahan

Province

Isfahan

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable