Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 31 3670 0666
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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
Isfehan
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
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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
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
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Person responsible for scientific inquiries

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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

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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
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