Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of L5-S1 interbody fusion on functional outcomes and radiological fusion rate following spinal fixation and fusion surgeries including S1 in lumbar canal stenosis patients

Protocol summary

Study aim
Investigating the effect of L5-S1 interbody fusion on functional outcomes and radiological fusion rate following spinal fixation and fusion surgeries including S1 in lumbar canal stenosis patients

Design
Controlled clinical trial, with parallel groups, double blind, randomized, phase2, on 32 patients. For randomization Rand function of Excel software was used

Settings and conduct
This study is conducted in patients with LCS who are admitted to the neurosurgery department of Imam Khomeini Hospital in Tehran for surgery. Patients will be allocated to two treatment and control groups by randomization. Double blinding of the evaluating doctor and the patients will be done

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Age>18 years 2-Lumbar canal stenosis(LCS)patients with indications for lumbosacral spine fixation and decompression surgery 3-Evidence of LCS based on MRI according to Boden criteria 4-Fixation and fusion have been done in maximum 5 levels 5-The patient has an indication for screw fixation at S1 level (S1 screw) 6-The patient has undergone interbody fusion with Posterior lumbar interbody fusion (PLIF) method 7-More than 50% of the graft used in the operation area should be autograft Exclusion criteria: 1-Response to non-surgical treatments 2-Vertebral fracture, tumor or infection, inflammatory spondylopathy and/or grade III and IV spondylolisthesis. 3-Suspicion of osteoporosis 4-Use of triparatide (Sinopar) 5-Scoliosis with a Cobb angle>25 degrees 6-Sagittal imbalance with Sagittal vertical axis(SVA)>9cm 7-Hip flexion contracture based on Thomas test 8-L5-S1 disc space is collapsed and fused 9-Unilateral L5-S1 instrument

Intervention groups
Intervention group:With L5-S1 interbody fusion Control group:Without L5-S1 interbody fusion

Main outcome variables
Radiological fusion rate of the spine at L5-S1level;Low back and lower limbs pain with VAS; Oswestry disability index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110829007441N4**
Registration date: **2022-12-06, 1401/09/15**
Registration timing: **prospective**

Last update: **2022-12-06, 1401/09/15**
Update count: **0**

Registration date
2022-12-06, 1401/09/15

Registrant information

Name
Hooshang Saberi

Name of organization / entity
Brain and Spinal Injury research center, Tehran university of medical sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-11, 1401/09/20

Expected recruitment end date
2024-12-31, 1403/10/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of L5-S1 interbody fusion on functional outcomes and radiological fusion rate following spinal fixation and fusion surgeries including S1 in lumbar canal stenosis patients

Public title
Investigating the effective causes in the improvement of pain and disability caused by low back pain, as well as the improvement of imaging findings after lumbar spine surgery, which includes the first sacral vertebra, in patients with lumbar canal stenosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient consent to participate in the research project Age> 18 years Confirmation of the diagnosis of lumbar spinal stenosis based on clinical examinations and imaging findings by neurosurgeon and spine and radiologist colleagues. Chronic low back pain for more than six months, persistent low back pain with or without shooting pains to the upper leg, neurogenic claudication, focal tenderness above the lumbar vertebral joint, and hyperextension pain leading to sensory or motor neurological deficit or inability to perform daily tasks Lumbar canal stenosis patients with indications for lumbosacral spine fixation and decompression surgery including: radicular syndrome, failure to respond to non-surgical treatments (rest, medical treatment, physical therapy), foraminal and lateral recess stenosis without central canal stenosis, pain related to disc herniation with radicular symptoms based on radiological or neurological tests (neurological tests include straight-leg raising test, suppress of reflex, motor weakness, sensory dysfunction), cauda equina syndrome, deformity (scoliosis) with an angle of less than 25 degrees in lumbosacral spine, grade I and II spondylolisthesis Evidence of lumbar spinal stenosis based on MRI according to Boden criteria Fixation and fusion have been done in maximum 5 levels for the patient The patient has an indication for screw fixation at S1 level (S1 screw), including L5-S1discectomy, L5-S1 spondylolisthesis, Kissing facet that requires facetectomy. The patient has undergone interbody fusion with Posterior lumbar interbody fusion (PLIF) method More than 50% of the graft used in the operation area should be autograft Iranian citizenship It is possible to follow up the patient and be available to participate in routine follow-up sessions
Exclusion criteria:
Response to non-surgical treatments Vertebral fracture, tumor or infection in the lumbosacral spine, inflammatory spondylopathy and grade III and IV spondylolisthesis. Suspicion of osteoporosis based on lumbosacral radiography (bone densitometry is done to prove the disease in suspected cases and the loss of bone density (T score less than -2.5) which is average for a healthy and adult person of the same age as osteoporosis Considered to be) Use of triparatide (Sinopar) Scoliosis with a Cobb angle of more than 25 degrees Sagittal imbalance with Sagittal vertical axis (SVA) greater than 9 cm Hip flexion contracture based on Thomas test L5-S1 disc height is not suitable before the operation and this space is collapse and fuse Unilateral L5-S1 instrument Revision surgery pregnant women contraindications for MRI People who do not want to participate in the study despite explaining the benefits of the project and the efforts of the study team to participate People who are not able to communicate in order to respond, such as deaf, blind people, speech problems, etc. People suffering from mental disorders, mental retardation and any psychiatric disorder in the acute stage such as psychosis, who are not treated and are unable to cooperate.
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization: Random allocation of patients will be produced and implemented by a list created by a computer by a researcher who does not cooperate in the clinical part of the trial. Randomization by stratified randomization method will be done based on two neurosurgeon by whom the patients will be operated on, as they will be classified into two groups, neurosurgeon A and neurosurgeon B, to control the confounding effect of the surgeon. Then the patients will be assigned to two treatment and control groups, and for its implementation, the sealed-envelope method will be used, which will be provided to the independent treatment group immediately before the operation. This will be done by an independent person who is unaware of the intervention allocated to the participants.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding: In this study, double blinding will be used. The blinding of the evaluating physician will be in such a way that the evaluating physician is unaware of the type of treatment performed for each patient. Also, the patients do not know the type of treatment they received until the end of the study.
Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini hospital complex, Tehran University of Medical Science

Street address

Imam Khomeini Hospital Complex, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.527

Health conditions studied

1

Description of health condition studied

Lumbar canal stenosis

ICD-10 code

M99.53

ICD-10 code description

Intervertebral disc stenosis of neural canal of lumbar region

Primary outcomes

1

Description

Radiological fusion rate of the spine at L5-S1 level

Timepoint

6 month after operation

Method of measurement

Standing lateral and flexion-extension lumbosacral X-ray and determination of fusion rate according to Brantigan-Steffee classification

Secondary outcomes

1

Description

Post-operative complications

Timepoint

After the operation and during the follow-up

Method of measurement

Based on the observations of the surgeon and the patient's medical record and imaging findings after the operation and during the follow-up

2

Description

The patient's pain level based on Visual Analogue Scale (low back pain and lower limb pain) after the operation

Timepoint

Before the operation, 2 weeks and 6 months after the operation

Method of measurement

Visual analog scale (Low back pain, Lower limb pain)

3

Description

Functional outcome of patient according to Oswestry disability index (ODI) after the operation

Timepoint

Before the operation, 2 weeks and 6 months after the operation

Method of measurement

Oswestry disability index (ODI)

4

Description

Patient satisfaction with postoperative recovery

Timepoint

2 weeks and 6 months after the operation

Method of measurement

Satisfaction questionnaire (Asking 4 questions to the patient)

Intervention groups

1

Description

Intervention group: With L5-S1 interbody fusion

Category

Treatment - Surgery

2

Description

Control group: Without L5-S1 interbody fusion

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
Dr Hooshang Saberi

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Sponsors / Funding sources

1

Sponsor

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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
Tehran University of Medical Sciences

Proportion provided by this source
50

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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Hooshang Saberi

Position
(Professor)

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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