Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the incidence of chronic sacroiliac joint pain (SIJP) following lumbar surgeries with and without lumbosacral spine fusion in spinal stenosis patients with low-grade lumbar degenerative spondylolisthesis using a non-randomized clinical trial study method.

Protocol summary

Study aim
Comparison of the frequency of SIJS sacroiliac joint syndrome after lumbar surgery with or without fusion

Design
A clinical trial with a control group, with parallel groups, without blinding and without randomization, on 106 patients with a follow-up length of three months.

Settings and conduct
review of similar studies from literature; Entering samples and performing surgery in two decompression groups with or without fusion; Follow-up of patients for three months after surgery; SIJ block in patients with SIJS diagnosis, measuring clinical function before and after surgery, after SIJS diagnosis and after SIJ block with VAS, ODI and Health Survey (SF-36) criteria and comparing the effect of SIJS and SIJ block on the results of these criteria

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 75 with Iranian citizenship and suffering from lumbar spinal canal stenosis with low-grade degenerative spondylolisthesis, without a history of lumbar spine surgery and after confirming the diagnosis with clinical examinations and imaging methods, who have not responded to non-surgical treatments, and It has a clear indication for decompression with the possibility of following up the patient and informed consent has been obtained from them.

Intervention groups
First and second intervention group: lumbosacral spine surgery with and without fusion The third and fourth intervention group: Sacroiliac joint anesthetic block in lumbosacral spine surgery patients with and without fusion who have sacroiliac joint syndrome after surgery

Main outcome variables
Change in SF-36 index and ODI index scores one and three months after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231127060204N1**
Registration date: **2024-05-07, 1403/02/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-07, 1403/02/18**
Update count: **0**

Registration date
2024-05-07, 1403/02/18

Registrant information

Name
Toufigh Mohaddes Javadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-04, 1403/02/15

Expected recruitment end date
2024-11-05, 1403/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the incidence of chronic sacroiliac joint pain (SIJP) following lumbar surgeries with and without lumbosacral spine fusion in spinal stenosis patients with low-grade lumbar degenerative spondylolisthesis using a non-randomized clinical trial study method.

Public title
Investigating the effect of lumbosacral spine fusion in the occurrence of sacroiliac joint syndrome (SIJS) after lumbar surgery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining written informed consent from the patient to participate in the study Age over 18 years Age below 75 years Patients suffering from lumbar spinal canal stenosis along with low grade degenerative spondylolisthesis of the lumbar spine which has been examined by clinical examinations and imaging methods and their disease has been confirmed by a neurosurgeon and spine specialist and a radiologist Ineffectiveness of non-surgical conservative methods in controlling the patient's symptoms and pain and disability No history of lumbar spine surgery Presence of a clear indication for decompression with or without fusion in the patient Having Iranian citizenship It is possible to follow up the patient and be available to participate in routine follow-up sessions
Exclusion criteria:
Vertebral fracture tumoral or metastatic lesions of vertebrae Infection in the lumbosacral spine Inflammatory spondylopathy Presence of SIJ disease Patients who have already undergone lumbosacral spine surgery, including revision cases Interior fusion indication (insertion of interbody cage) Chronic pain problems, such as Fibromyalgia and other Rheumatological diseases, chronic pain associated with inflammation or irritation of the muscle or fascia around the muscle Suspicion of Osteoporosis based on simple lumbosacral radiography (Bone Densitometry is performed to prove the disease in suspected cases) People who have Scoliosis with a Cobb angle of more than 25 degrees Sagittal Imbalance with (Sagittal Vertical Axis - SVA) more than 9 cm Presence of Hip flexion contracture based on examination with Thomas test Simultaneous surgical indication of lumbar canal stenosis and cervical canal stenosis Pregnant women Presence of contraindications for MRI The patient's unwillingness to participate in the study despite explaining the benefits of the plan and the efforts of the study team to attract their participation People who are unable to communicate in order to answer study questions, such as Deaf, Blind, Speech problems People suffering from Mental and Psychological disorders, Mental retardation and any Psychiatric disease in the acute stage such as Psychosis, who have not been treated and are unable to cooperate Sciatica pain radiating below the knee, work injury, litigation
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Educational, Research and Treatment Center of Dr. Shariati Hospital - Tehran University of Medical S
Street address
No.10, 8th Alley, North Mosaddegh St, Mirdamad Blvd.
City
Tehran
Province
Tehran
Postal code
1918885553
Approval date
2023-07-16, 1402/04/25
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.067

Health conditions studied

1

Description of health condition studied
sacroiliac joint pain
ICD-10 code
M46.1
ICD-10 code description
Sacroiliitis, not elsewhere classified

2

Description of health condition studied
Spondylosis, arthrosis or osteoarthritis of spine, degeneration of facet joints
ICD-10 code
M47
ICD-10 code description
Spondylosis

3

Description of health condition studied
Spondylolisthesis
ICD-10 code
S33.1
ICD-10 code description
Subluxation and dislocation of lumbar vertebra

4

Description of health condition studied
spondylosis with myelopathy
ICD-10 code
M47.1
ICD-10 code description
Other spondylosis with myelopathy

5

Description of health condition studied
spondylosis with radiculopathy
ICD-10 code
M47.2
ICD-10 code description
Other spondylosis with radiculopathy

6

Description of health condition studied
Other spondylosis
ICD-10 code
M47.8
ICD-10 code description
Other spondylosis

7

Description of health condition studied
Spondylosis, unspecified
ICD-10 code
M47.9
ICD-10 code description
Spondylosis, unspecified

8

Description of health condition studied
Spinal stenosis
ICD-10 code
M48.0
ICD-10 code description
Spinal stenosis

9

Description of health condition studied
Spondylopathy, unspecified
ICD-10 code
M48.9
ICD-10 code description
Spondylopathy, unspecified

Primary outcomes

1

Description
Change in SF-36 Quality of life index summary score
Timepoint
One month and 3 months after surgery
Method of measurement
Quality of life Criteria: The patients' perception of their health status in life and their level of satisfaction with this situation will be recorded and stored in the study plan database in three stages according to the items listed in the above measurement and for final analysis. In this study, the 36-question quality of life questionnaire (SF-36) will be used, which has 36 questions and consists of 8 subscales, and each subscale consists of 2 to 10 items. The eight subscales of this questionnaire are: 1) Physical function (PF) 2) Role disruption due to physical health (RP) 3) Role disruption due to emotional health (RE) 4) Energy/fatigue (EF) 5) Emotional well-being (EW) 6) social function (SF) 7) pain (P) 8) general health (GH). Due to the complexity of scoring this questionnaire, its full scoring takes place in several stages. Also, at the end of scoring, two general subscales will be obtained for this questionnaire, which are: 1) physical health subscale, 2) mental health subscale

Secondary outcomes

1

Description
Change in ODI Disability Index score
Timepoint
One month and 3 months after surgery
Method of measurement
The degree of disability caused by back pain will also be measured in three stages according to the above mentioned times and will be recorded and stored in the database software of the study plan. The Oswestry Disability Index (ODI) questionnaire will be used to measure the level of patients' inability to perform daily activities, which includes 10 sections and each section has a score between 0 and 5, where a score of 0 equals "no pain" and a score of 5 equals " "The worst pain imaginable for the patient", so the first sentence in each section has zero points and the last sentence has 5 points. Therefore, the total raw score will be between zero and 50 points, and a higher score indicates more disability in the patient. To express the test result as a percentage, multiplying the raw score by 2 will be used.

Intervention groups

1

Description

The first intervention group: lumbosacral spine surgery with fusion.Patients undergo surgery in one of two ways. Decompression group without fusion and decompression group plus fusion (instrumental using screw and titanium rod). In the first intervention group, patients diagnosed with low-grade lumbar spondylolisthesis with lumbar stenosis and neurogenic lameness with or without lumbar radiculopathy and lumbar instability in flexion-extension radiography of the lumbar spine (movement of more than 3 to 14 mm at the level of listhesis) are included. Decompression and fusion surgery group. In all fusion patients, autogenous bone graft with the origin of lamina and spinous process was used. After surgery, patients enter the follow-up phase for three months and are monitored after one month and three months in terms of the occurrence of new back pain that is different from preoperative pain that is consistent with the criteria of sacroiliac joint syndrome (SIJS). And if SIJS occurs and is confirmed, they enter the next intervention phase (anesthetic block of the SIJ joint).

Category

Treatment - Surgery

2

Description

The second intervention group: lumbosacral spine decompression surgery without fusion.Patients undergo surgery in one of two ways. Decompression group without fusion and decompression group plus fusion (instrumental using screw and titanium rod). In the second intervention group, patients diagnosed with low-grade lumbar spondylolisthesis with lumbar stenosis and neurogenic lameness with or without lumbar radiculopathy without lumbar instability in flexion-extension radiography of the lumbar spine (movement less than 3 mm at the level of listhesis) are included in the surgical group. Decompression without fusion. After surgery, these patients enter the follow-up phase for three months and are monitored after one month and three months in terms of the occurrence of new back pain that is different from preoperative pain that is consistent with the criteria of sacroiliac joint syndrome (SIJS). and if SIJS occurs and is confirmed, they enter the next intervention phase (anesthetic block of the SIJ joint).

Category

Treatment - Surgery

3

Description

The third intervention group: Sacroiliac joint anesthetic block in lumbosacral spine surgery patients with fusion who have sacroiliac joint syndrome after surgery.After surgery, patients in the intervention groups of decompression with fusion and decompression without fusion enter the follow-up phase for three months. In the third intervention group, at each stage of follow-up (first and third month after surgery), each of the patients of the first and second intervention groups who have persistent back pain and new point tenderness whose pain is unilateral (or with unilateral spread) ; with diffusion topography consistent with sacroiliac origin, without diffusion below the knee, sacroiliac groove tenderness to palpation; positive at least 3 sacroiliac joint provocative examinations (thigh thrust, FABER, compression, Gaenslen's, distraction) and the absence of lumbar causality evidence (especially the absence of destruction of the adjacent disc in MRI and the absence of pseudarthrosis) with the diagnosis of sacroiliac joint syndrome (SIJS)) enter the next intervention phase and are placed under the SIJ block. At each stage, the outcome is measured based on ODI and SF-36 criteria in the stage before injection and block and VAS criteria after injection.The criteria for positive provocative maneuvers to diagnose SIJ as the main source of pain includes the possibility of reproducing the patient's typical pain in the SIJ region; A positive test as a possible case and a positive 3 or more tests as a very likely case of SIJS is considered as a pain generator.In the detailed description of the intervention to perform the block, the skin over the sacroiliac joint is anesthetized with 1% lidocaine using a short needle. Carefully avoiding anesthetizing the periarticular ligaments, a 20-gauge 50mm needle is inserted into the lower part of the joint. One milliliter of non-ionic contrast material is injected to confirm the placement of the needle inside the joint, and then the joint is anesthetized with 2.5 milliliters of lidocaine 2% + 1 milliliter of triamcinolone + 1.5 milliliters of distilled water (5 milliliters in total). The amount of pain before the block was based on the VAS scale with the question "How much was your average pain this morning?" It was measured and measured again 15 minutes after the block and after 5 minutes of walking and sitting. The criteria for a positive block will include accurate injection of contrast inside the joint, as well as pain relief of the patient up to 75%. A positive block will be considered to confirm the diagnosis of sacroiliac syndrome.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr Ahmad Reza Jamshidi

Street address

Dr. Shariati Research and Treatment Center, in front of Faculty of Economics, Jalal Al Ahmad Street, North Kargar St.

City

Tehran

Province

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1411713135

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Email
shariatihosp@tums.ac.ir

Web page address
https://shariati.tums.ac.ir/

2

Recruitment center

Name of recruitment center
Yas Hospital Complex

Full name of responsible person
Dr Arash Jafarieh

Street address
Yas Hospital Complex, next to Urban Land Organization, at the end of North Ostad Nejatullahi Street (former villa), Karimkhan Zand Street

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Tehran

Province
Tehran

Postal code
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Phone
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Fax
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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Ali Akbari Sari

Street address
Tehran University of Medical Sciences Headquarters, corner of Qods St., Keshavarz Boulevard

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Province
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Email
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Web page address
https://tums.ac.ir/

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
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
Tehran University of Medical Sciences

Full name of responsible person
Toufigh Mohaddes Javadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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Position
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Latest degree
Medical doctor

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Neurosurgery

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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
Neurosurgery
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Email
toufighmj@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data of study participants including total data after de-identification of individuals
When the data will become available and for how long
The access period starts from February 2024
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The user of the clinical reports of this study should: 1- Do not use the results of this study for non-research or commercial purposes. 2- To ensure that the use of this clinical study report always complies with applicable laws. 3- Don't misrepresent the source of clinical reports from this study. 4- Do not seek to re-identify the trial subjects or other people from the clinical reports of this study in violation of privacy laws. The user of the clinical reports of this study should not: 1- Use the clinical reports of this study to support an application for marketing authorization and any extension or modification of a product anywhere in the world. 2- Do not share the available information or the results of the data analysis of this study with any third party. 3- Any commercial and non-medical research use of the clinical reports of this study is against the consent of the researcher of this study and violates the privacy of the study participants and will be prosecuted.
From where data/document is obtainable
Mailbox: Toufighmj@gmail.com Telegram: @toufighmj Cell: 00989143118540 Toufigh Muhaddes Javadi
What processes are involved for a request to access data/document
1- Authentication as a medical researcher 2- Introducing a study that needs to use the reports of this study. 3- Send an e-mail request with the above documents, stating the reasons for the need for access and agreeing to comply with all the conditions listed in the conditions and objectives section of the subscription and using the results of this study in other clinical and research studies.
Comments