Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Transpedicular fixation with fusion with transpedicular fixation alone in spondylolisthesis

Protocol summary

Study aim
In instances of 1st and 2nd grade degenerative lumbar spondylolisthesis treated with transpedicular fixation with or without interbody fusion via lumbar cage, the goal of this study is to assess the short-term clinical and outcome outcomes of two surgical procedures.

Design
Randomized, superiority, parallel group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site, sample size 28.

Settings and conduct
A trial was conducted at Afridi medical complex, Peshawar. In the Randomized Controlled Trial (RCT), outcome assessors were blinded through a meticulous process where they were kept unaware of participants' assigned interventions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1st and 2nd grade degenerative lumbar spondylolisthesis patients and patients who would consent to participate under ethical conditions Exclusion criteria: 1) Patients with additional lumbar spondylolisthesis types; 2) Patients with additional lumbar degenerative spondylolisthesis grades (3rd and 4th grades); 3) Patients with additional spine pathology (lumbar fracture, disc prolapse)

Intervention groups
Group A: Participants randomized to group, undergoing transpedicular fixation with Fusion, will receive bilateral transpedicular fixation using pedicle screws, coupled with interbody fusion employing autograft or suitable bone substitute. This will be complemented by posterior stabilization using rods and cross-links. Group B: Group B, designated for Transpedicular Fixation Alone, will involve bilateral transpedicular fixation with pedicle screws without interbody fusion, followed by posterior stabilization using rods and cross-links.

Main outcome variables
The Oswestry Disability Index (ODI) and Visual Analogue Score (VAS)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230907059376N3**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **retrospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date
2023-12-09, 1402/09/18

Registrant information

Name
Sarmad Khattak

Name of organization / entity
Rehman Medical Institute, Peshawar

Country
Pakistan

Phone
+92 91 5838666

Email address
sarmadkhattak007@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-21, 1400/05/30

Expected recruitment end date
2022-06-27, 1401/04/06

Actual recruitment start date
2021-11-23, 1400/09/02

Actual recruitment end date
2022-12-18, 1401/09/27

Trial completion date
2023-12-29, 1402/10/08

Scientific title
Comparison of Transpedicular fixation with fusion with transpedicular fixation alone in spondylolisthesis

Public title
Comparison of transpedicular fixation with fusion with transpedicular fixation alone in spondylolisthesis: A Randomized Control Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
First and second grade degenerative lumbar spondylolisthesis patients Patients who would consent to participating in the study under ethical conditions Both Gender Male and Female Age 18-45 years

Exclusion criteria:
Patients with additional lumbar spondylolisthesis types Patients with additional lumbar degenerative spondylolisthesis grades (3rd and 4th grades) Patients with additional spine pathology (lumbar fracture, disc prolapse) Patients who respond to conservative treatment

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **28**
Actual sample size reached: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were grouped based on center and randomly assigned using a computer-generated permuted-block system. Allocations were kept in opaque, coded, and sealed envelopes by a data manager who was not engaged in the patient selection or allocation process. Following randomization, the prepared envelope was opened, the patient was told of the assigned intervention, and the necessary preparations were made for the assigned intervention.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the Randomized Controlled Trial (RCT), outcome assessors were blinded through a meticulous process where they were kept unaware of participants' assigned interventions. This ensured the assessments were conducted objectively, minimizing bias and enhancing the reliability of the trial's results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Afridi medical complex ethical commette

Street address
Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa 25150

City
Peshawar

Postal code
25150

Approval date
2021-07-09, 1400/04/18

Ethics committee reference number
03420-1

Health conditions studied

1

Description of health condition studied
Spondylolisthesis

ICD-10 code
M43.1

ICD-10 code description
Spondylolisthesis

Primary outcomes

1

Description
Lumbar spine disability

Timepoint
Post-surgery for baseline and then after 6 and 12 months

Method of measurement
Oswestry Disability Index (ODI)

2

Description
Pain

Timepoint
Post-surgery for baseline and then after 6 and 12 months

Method of measurement
Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants randomized to intervention group, undergoing Transpedicular Fixation with Fusion, will receive bilateral transpedicular fixation using pedicle screws, coupled with interbody fusion employing autograft or suitable bone substitute. This will be complemented by posterior stabilization using rods and cross-links.
Category
Treatment - Surgery

2

Description
Control group: Group B, designated for Transpedicular Fixation Alone, will involve bilateral transpedicular fixation with pedicle screws without interbody fusion, followed by posterior stabilization using rods and cross-links.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Afridi Medical Complex, Peshawar
Full name of responsible person
Muhammad Idris Khan
Street address
Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa 25150
City
Peshawar
Postal code
25150
Phone
+92 335 0907875
Email
idrisnsw83@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Afridi Medical Complex, Peshawar
Full name of responsible person
Mahboob Khan
Street address
Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa
City
Peshawar
Postal code
25150
Phone
+92 91 5711751
Email
mehboob509@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Afridi Medical Complex, Peshawar
Proportion provided by this source
50
Public or private sector
Private
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
Afridi Medical Complex, Peshawar
Full name of responsible person
Mahboob Khan
Position
Consultant Neurosurgeon
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Afridi medical complex tehkal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa
City
Peshawar
Province
Khyber Pakhtunkhwa
Postal code
25150
Phone
+92 91 5711751
Email
mehboob509@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Afridi Medical Complex, Peshawar
Full name of responsible person
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Position
Consultant Neurosurgeon
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Other areas of specialty/work
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Peshawar

Province
Khyber Pakhtunkhwa

Postal code
25150

Phone
+92 91 5711751

Email
mehboob509@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rehman Medical Institute, Peshawar

Full name of responsible person
Sarmad Khattak

Position
Resident Surgeon

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

Street address
House No. 245 Street 7 Sector N 2 Phase 4 Hayatabad Peshawar

City
Peshawar

Province
Khyber Pkahtunkhwa

Postal code
25000

Phone
+92 91 5838666

Fax

Email
sarmadkhattak007@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
Data will be available in the document under the title name, "Transpedicular fixation with fusion vs Transpedicular fixation alone in spondylolisthesis: A Randomized Control Trial"

When the data will become available and for how long
Data will be available after study is published for a year.

To whom data/document is available
Data will be available for researchers and neurosurgeons as well as neuro physicians.

Under which criteria data/document could be used
Data will be used by giving credit to the Principal investigator, Dr. Muhammad Idris Khan consultant Neurosurgeon.

From where data/document is obtainable
Documents will be provided through email to the Principal author Dr. Muhammad Idrees Khan (idrisnsw83@gmail.com)

What processes are involved for a request to access data/document
Documents will be provided through email to the Principal author Dr. Muhammad Idrees Khan (idrisnsw83@gmail.com)

Comments