

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 commettee

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

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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

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Postal code

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Phone

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

Position

Consultant Neurosurgeon

Latest degree

Specialist

sarmadkhattak007@gmail.com

Other areas of specialty/work

Neurosurgery

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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

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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