

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Analysis of correlation between the pedicular screw diameter to pedicle width ratio and the rate of fusion and surgery complications in Posterior Lumbar Interbody Fusion surgery

Protocol summary

2023-07-25, 1402/05/03

Study aim

Analysis of correlation between the pedicular screw diameter to pedicle width ratio and the rate of fusion and surgery complications in Posterior Lumbar Interbody Fusion surgery

Design

A randomized, double-blind, controlled clinical trial

Settings and conduct

The study will be conducted as a blind clinical trial. The site of the study will be Imamreza Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates to the spinal fixation surgery. Exclusion criteria: People with underlying diseases such as high blood pressure, diabetes and severe osteoporosis. Patients with kidney failure. Patients with metastases, tumor and scoliosis. Overweight (BMI > 30)

Intervention groups

Patients fall under the fusion with a pedicle screw of different sizes. The first fallowian of complications is 3 times and then 6 months after the surgery.

Main outcome variables

The pedicular screw diameter to pedicle width ratio, Mean volume of bleeding, Mean of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N17**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

Registration date

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-11-01, 1402/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analysis of correlation between the pedicular screw diameter to pedicle width ratio and the rate of fusion and surgery complications in Posterior Lumbar Interbody Fusion surgery

Public title

Correlation between the pedicular screw diameter to pedicle width ratio in Fusion surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates to the spinal fixation surgery Agreed to participator

Exclusion criteria:

People with underlying diseases such as high blood pressure, diabetes and severe osteoporosis Patients with kidney failure Patients with metastases, tumor and scoliosis Overweight (BMI>30)

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz Medical School

Street address

Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5159115705

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

IR.TBZMED.REC.1402.055

Health conditions studied**1****Description of health condition studied**

Spinal fusion

ICD-10 code

M99.3

ICD-10 code description

Osseous stenosis of neural canal

Primary outcomes**1****Description**

The pedicular screw diameter to pedicle width ratio

Timepoint

During surgery

Method of measurement

Radiography

2**Description**

Mean volume of bleeding

Timepoint

All the time of operation

Method of measurement

To measure the volume of suctioned blood and weigh the collected gauze from the field

Secondary outcomes**1****Description**

Mean of pain

Timepoint

3 and 6 months after surgery

Method of measurement

Pain Visual Analog Questionnaire

2**Description**

The amount of pseudoarthrosis

Timepoint

3 and 6 months after surgery

Method of measurement

Radiography

Intervention groups**1****Description**

Intervention group:Patients fall under fusion with pedicle screws of different sizes and will be divided based on whether the pedicle screws occupy less than 50%, between 50% and 75%, and more than 75% of pedicle width,then the complications will be checked after 3 months and 6 months after surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

Dr.Ghafar Shokouhi

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

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5166614756

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+98 914 114 4484

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joyban

Street address

Vice chancellor for research, Daneshgah street, Tabriz

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ghafar Sokouhi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Moslem Shakeri

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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Bishli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A portion of the data that represents the final outcome

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For modeling and guidance

From where data/document is obtainable

The person responsible for updating study information

What processes are involved for a request to access data/document

The applicant provides information about their application via email. Up to two weeks after the request, if accepted, documents or data files will be sent.

Comments