Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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 fallopian 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
2023-07-25, 1402/05/03

Registrant information

Name
Firooz Salehpour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 41 3334 0830

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Dr. Moslem Shakeri

Position
Associate professor

Latest degree
Specialist

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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

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Resident
Latest degree
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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