

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of rod contouring on the normal lumbar spine curvature in the one level fusion.

Protocol summary

Study aim

The effect of rod contouring on the normal lumbar spine curvature in the one level fusion

Design

Patients undergoing surgery will be divided into three random groups using the www.random.org by the Gaussian Generator order. After random assignment of the study groups, the A, B labels were assigned to the target group by the secretary. Then, the patients will be intervened by the researcher in the operating room in the case group. All persons involved in the study will be unaware of the type of intervention performed.

Settings and conduct

Imam Reza Hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: Traumatic fractures of type of compression, sprain and fracture due to spinal flexure Which require surgery Severe spinal canal stenosis Completion of informed consent form exclusion criteria: Traumatic fractures of type of fracture-in-depression Pathological fractures Fracture in several vertebrae Head trauma simultaneous with vertebral fracture A neurological condition in which neurological examination is not possible for

Intervention groups

Control group (A): After the patient's preparation, fixation and posterior fusion will be done using a pedicle screw. After the rod is inserted, the fusion will be effected by autograft, which will be made from the vagus and laminae of the vertebrae. In this case The stage of action will end upon radical curvature Intervention group (B): After the patient's preparation, fixation and posterior fusion will be done using a pedicle screw. After the rod is inserted, the fusion will be effected by autograft, which will be obtained from the lobe and the lamina of the vertebrae. Rads will not be entered

Main outcome variables

vertebral fusion At the beginning of the study, 6 months after the intervention Using radiological evaluations and

physical examination using visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N9**

Registration date: **2019-07-05, 1398/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-05, 1398/04/14**

Update count: **0**

Registration date

2019-07-05, 1398/04/14

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

2019-03-06, 1397/12/15

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of rod contouring on the normal lumbar spine curvature in the one level fusion.

Public title
Study the effect of curvature on the spinal cord in maintaining normal curvature of the spine

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Lumbar lordosis approval using graph Complaint of lumbar lordosis caused by lumbar pain
Exclusion criteria:
Pain caused by radiculopathy Having a kayape History of surgery on the spine

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients undergoing surgery will be divided into two random groups using the www.random.org

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

tabriz hotel marmar

City

tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TBZMED.REC.1397.1098

Health conditions studied

1

Description of health condition studied

spinal fractures and spinal canal stenosis

ICD-10 code

S32.0

ICD-10 code description

Fracture of lumbar vertebra

Primary outcomes

1

Description

Lumbar vertebral fusion

Timepoint

At the beginning of the study, 6 months after the intervention

Method of measurement

Using radiological evaluations and physical examination using visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group (A): After the patient's preparation, fixation and posterior fusion will be done using a pedicle screw and the rod will be inserted. Then the fusion will be effected by the otograft, which is obtained from the spinous process and the lamina of the vertebrae, and at this stage the action will be terminated

Category

Treatment - Surgery

2

Description

ntervention group (B): After preparing the patient, fixation and posterior fusion are completed using a pedicle and after the installation of the Rod, the fusion will be effected by the otograft, which is obtained from the spinous process and the lamina of the vertebrae. Then a cross link is placed in the central part of the structure and the instrumentation process will end.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

Taher mousavi

Street address

Emam Reza Hospital, Daneshgah Ave, Pishghadam
Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Iraj Lotfinia

Street address

Vice Chancellor for Research , Faculty of Medicine ,
Gholghasht Street, Azadi Street, Tabriz

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info@medfac.tbzmed.ac.ir

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

Iraj lotfinia

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

تبریز - خیابان آزادی - خیابان گلگشت - بیمارستان امام رضا -
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

دکتر فیروز صالح پور

Position

professor

Latest degree

Specialist

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

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

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

Access will be 6 months after the results are printed

To whom data/document is available

All Physicians and residents of the department of neurosurgery

Under which criteria data/document could be used

After obtaining permission from the deputy research group

From where data/document is obtainable

En Person responsible for scientific accountability study

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

First approved by the Research Vice-President

Comments