Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of Cross-linkage between pedicular screws for fusion in patient with traumatic thoracolumbar vertebral fractures

Protocol summary

Study aim
Evaluation of the effect of Cross-linkage between pedicular screws for fusion in patient with traumatic thoracolumbar vertebral fractures

Design
The study is a randomized, community-based, and pragmatic clinical trial consisting of 60 patients in 3 parallel groups with double-blind design.

Settings and conduct
This study was performed on 60 patients with thoracolumbar vertebral fractures due to spinal cord trauma referring to Tabriz Imam Hospital. All patients received initial neurological evaluation of trauma and medical emergencies through a complete neurological examination. Thoracolumbar spine radiography and CT scan was performed by triple reconstruction in axillary and sagittal and coronal segments and MRI was performed in the axillary and sagital segments after admission.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Spinal fracture based on Denis model except fractures-deformity fractures, 2) TLCS score above 4, 3) Completion of informed consent form Exit criteria: 1) Pathological fracture 2) Multiple vertebral fractures 3) Synchronous head trauma 4) Neurological defects before fracture 5) Non-neurological examinations 6. Fracture-fracture fractures

Intervention groups
Control group (A): After the patient's preparation, fixation and posterior fusion will be done using a pedicure screw. After the rod is inserted, the fusion will be done by autograft, which is obtained from the caryophylline and laminae of the vertebrae. In this group, the intervention will end at this stage. Intervention group (B): A cross-link will be embedded in the middle of the structure and instrumentation process will be terminated. Intervention group (C): Two cross-links, one at the lower end and one at the upper end of the structure, and the instrumentation process will be terminated.

Main outcome variables
Bone fusion rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120527009878N3**
Registration date: **2018-09-13, 1397/06/22**
Registration timing: **retrospective**

Last update: **2018-09-13, 1397/06/22**
Update count: **0**

Registration date
2018-09-13, 1397/06/22

Registrant information
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Firooz Salehpour
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Cross-linkage between pedicular screws for fusion in patient with traumatic thoracolumbar vertebral fractures

Public title
The effect of using interface between right and left screws on bone formation around broken vertebrae

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Traumatic fractures of type of compression, sprain and fracture due to spinal flexure Thoracolumbar Injury Classification and Severity Score (TILCS) more than 4 Completing the 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 the patient at the time of admission Having a nerve defect before the spinal trauma

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients undergoing surgery will be divided into three random groups using the www.random.org by the Gaussian Generator order.

Blinding (investigator's opinion)
Double blinded

Blinding description
After random assignment of the study groups, the A, B and C 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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Science

Street address
Tabriz University of Medical Science , Gholghasht street , Azadi street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2018-08-06, 1397/05/15

Ethics committee reference number
IR.TBZMED.REC.1397.390

Health conditions studied

1

Description of health condition studied
Traumatic thoracolumbar vertebral fractures

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 (A): After the patient's preparation, fixation and posterior fusion will be done using a pedicure screw and the rod will 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

Intervention 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

3

Description

Intervention group (C): After the patient's preparation, fixation and posterior fusion will be done using a pedicure screw. After the rod is inserted, the fusion will be effected by otograft, which is obtained from the spinous process and the lamina of the vertebrae. Then, two cross-links, one at the lower end and one at the upper end of the structure, will be completed and the instrumentation process will be completed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

Full name of responsible person

Mir Bagher Matloubi Sis

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

Dr. Ghaffar Shokuhi Tabrizi

Street address

Vice Chancellor for Research , Faculty of Medicine , Gholghasht Street, Azadi 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. Ghaddar Shokuhi Tabrizi

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
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