

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 sagittal 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 pedicle 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

##### 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

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

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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 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**

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 pedicle 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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info@imamreza.tbzmed.ac.ir

**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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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Firoz Salehpoor

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

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Dr. Firoz Salehpoor

**Position**

Professor

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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**