

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Results of alendronate administration in patients with lumbar spine fracture without surgical indication

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the results of postoperative alendronate in patients with lumbar vertebral fracture without surgical signs.

##### Design

Parallel group randomised trial without blinded group

##### Settings and conduct

The present study will be carried out at Imam Reza Hospital in Tabriz, Iran, in the Department of Neurosurgery. Blind will not be done. Patients in the intervention group will receive Alendronate, and patients in the control group will receive the necessary supportive measures.

##### Participants/Inclusion and exclusion criteria

This study was a randomized clinical trial on 60 patients with thoracolumbar vertebral fractures due to spinal trauma referring to Tabriz Imam Reza Hospital without the indication of fusion surgery in the vertebral column. All patients will undergo a neurological assessment of neurological outcome while receiving initial treatments for trauma and standard treatments (NSAIDs and painkillers) and medical emergencies. Patients will be divided into random groups A and B by Randlist 2.1 software. Group A will receive Alendronate and Group B will receive analgesics. Group A patients will receive weekly 35 mg alendronate at a dose of 70 mg per week after discharge. Patients will not be deprived of standard treatment (NSAIDs, relief and other needed).

##### Intervention groups

Patients in the intervention group will receive weekly 35 mg of alendronate at a dose of 70 mg per week after discharge.

##### Main outcome variables

Patients with low back pain will be evaluated on the basis of the Visual Analogue Scale 6 months after receiving the drug.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101122005230N3**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

##### Registration date

2019-07-28, 1398/05/06

##### Registrant information

##### Name

Moslem Shakery

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1333 7927

##### Email address

shakerym@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-26, 1398/04/05

##### Expected recruitment end date

2019-07-23, 1398/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Results of alendronate administration in patients with lumbar spine fracture without surgical indication

## Public title

Alendronate effects in patients with lumbar spine fracture

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Lack of Indication for Surgery based on Thoracolumbar injury classification severity score Spinal cord fracture according to Denis model in CT Scan Informed consent to participate in the study

### Exclusion criteria:

Pathological fractures Fractures in several vertebrae Simultaneous head trauma and neurological status of the patient in such a way that it is not possible to have a neurological examination at the time of admission Neural failure before spinal trauma Fracture-type fracture-dislocation Disturbed results of calcium and serum vitamin D tests (osteoporosis)

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be divided into random groups A and B by Randlist 2.1 software. Group A will receive Alendronate and Group B Hemorrhage. Patients will be followed up for 6 months.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### 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

Neurosurgery Ward, Imam Reza Hospital, Golgasht Ave, Tabriz, Iran.

## City

Tabriz

## Province

East Azarbaijan

## Postal code

5166614756

## Approval date

2019-05-06, 1398/02/16

## Ethics committee reference number

IR.TBZMED.REC.1398.107

## Health conditions studied

### 1

#### Description of health condition studied

Pain after surgery

#### ICD-10 code

M54.5

#### ICD-10 code description

Low back pain

## Primary outcomes

### 1

#### Description

Pain after surgery

#### Timepoint

6 months after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After discharge, patients will receive weekly 35 mg of alendronate at a dose of 70 mg per week.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients will receive analgesics.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Dr Moslem Shakery

**Street address**

Imam Reza Hospital, Golgasht Street, Daneshgah Ave, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3334 7054

**Fax**

+98 41 3334 7054

**Email**

imamreza.hospital@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Moslem Shakeri

**Street address**

Vice Chancellor for Research, Tabriz University of Medical Sciences, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3334 7054

**Fax**

+98 41 3334 7054

**Email**

research@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**

Dr. Moslem Shakery

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Imam Reza Hospital, Golgasht Street, Daneshgah Ave, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 1333 7927

**Fax****Email**

shakerym@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Moslem Shakery

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Imam Reza Hospital, Golgasht Street, Daneshgah Ave, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 1333 7927

**Fax****Email**

shakerym@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Moslem Shakery

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Imam Reza Hospital, Golgasht Street, Daneshgah Ave, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 1333 7927

**Fax****Email**

shakerym@tbzmed.ac.ir

**Web page address**

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Study data is consistent with the ethical principles of privacy of the patients to be shared.

**When the data will become available and for how long**

After publication, the results are available in the form of a scientific article.

**To whom data/document is available**

Researchers can access data through action from the university or research center.

**Under which criteria data/document could be used**

Study data is available to compare results with other studies.

**From where data/document is obtainable**

Study data is available through the responsibility of trial updates.

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

Data is accessible by sending a request through academic email and providing valid identification documents.

**Comments**