Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 alendronitis 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
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Iran (Islamic Republic of)
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+98 41 1333 7927
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Moslem Shakeri

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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

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Person responsible for updating data

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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