

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of Alendronate and Vitamin D administration on lumbosacral vertebral fusion in patients undergoing posterior spinal cord fusion

Protocol summary

Study aim

Evaluation of the effect of Vitamin D and Alendronate on pseudoarthrosis of the lumbosacral vertebrae in patients undergoing posterior lumbar fusion surgery

Design

This study is a clinical trial with a blind and randomized parallel group design. Among the patients diagnosed with lumbar disc herniation, spinal canal stenosis, lumbar Listis was selected by 75 neurosurgeons and divided into three groups of 25: fusion, fusion and andronate, fusion and vitamin D by blocking method (method of randomization).

Settings and conduct

This study among patients requiring laminectomy and lumbar vertebral fusion with the pedicure screw is performed up to 5 vertebral surfaces, referring to Imam Sari Hospital. The study is single blind and the radiologist interprets the patient's CT stereotype without knowing the clinical picture and how to be in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: lumbar discopathic patients, spinal canal stenosis, lumbar listhesis, Cr <1.2, patients between 20 and 65 years of age. Non inclusion criteria: patients with traumatic lesions, neoplastic lesions, infectious lesions, surgical history, diabetes, disabling underlying problems and rheumatic diseases, patients with a history of osteoarthritis and vitamin D deficiency less than 10 units, patients with renal insufficiency and GFR below 40.

Intervention groups

Intervention group 1: Patients in the alendronate group were given 70 mg of oral alendronate once every 6 weeks after surgery for 6 months. Intervention group 2: they received 50,000 units of vitamin D per month for six months. Control group: Patients in the control group received routine treatment after surgery

Main outcome variables

Pain; vertebral fusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040869N2**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Misagh Shafizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

mi.shafizad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2020-01-31, 1398/11/11

Actual recruitment start date

2019-06-05, 1398/03/15

Actual recruitment end date

2020-03-15, 1398/12/25

Trial completion date

2020-03-18, 1398/12/28

Scientific title

Comparison of the effects of Alendronate and Vitamin D administration on lumbosacral vertebral fusion in patients undergoing posterior spinal cord fusion

Public title

Comparison of the effects of Alendronate and Vitamin D administration on lumbosacral vertebral fusion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Lumbar discopathy patients spinal canal stenosis lumbar Listis Cr <1.2 age between 20 and 65 years

Exclusion criteria:

Patients with traumatic lesions Neoplastic lesions Infectious lesions Surgical history Disabling underlying problems and rheumatic diseases Patients with a history of osteoarthritis and vitamin D deficiency less than 10 units Patients with renal insufficiency and GFR below 40

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

75 people were selected and divided into three groups of 25: fusion, fusion and alendronate, fusion and vitamin D by blocking method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The radiologist interpreted the patient's CT scan radiographs without knowing the clinical picture and how to be in the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sari Imam Hospital, Mazandaran University of Medical Sciences

Street address

Imam Hospital, Amirmazandarani boulevard

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.018

Health conditions studied**1****Description of health condition studied**

spinal fusion

ICD-10 code

M99.3

ICD-10 code description

Osseous stenosis of neural canal

Primary outcomes**1****Description**

Percentage of people with no fusion

Timepoint

Patients will be re-examined and fusion of the vertebrae one month, three months, and six months after surgery

Method of measurement

Check CT scan stereotype

2**Description**

Percentage of people with low pain scores

Timepoint

Patients will be re-examined for pain severity one month, three months, and six months after surgery

Method of measurement

From the visual analog scale vas (visual Analog Scale)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: In the Alendronate group, 70 mg of oral Alendronate was given as treatment every 6 weeks for 6 months.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients received 50,000,000 units of vitamin D per month for six months. In addition to the present treatments, physiotherapy and supportive therapies were also performed.

Category

Treatment - Drugs

3

Description

Control group: Control group: Patients in this group receive conventional treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sari Hospital

Full name of responsible person

Misagh Shafizad

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Amir Mazandarani Blvd ,Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

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Email

saedi@domian.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Misagh Shafizad

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Misagh Shafizad

Position

Consultant

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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