

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The efficacy of vitamin D and oral alendronate in patients with low back pain and modic changes who underwent lumbar fusion surgery.

Protocol summary

Study aim

The efficacy of vitamin D and oral alendronate in patients with low back pain and modic changes who underwent lumbar fusion surgery.

Design

The efficacy of vitamin D and oral alendronate in patients with low back pain and modic changes who underwent lumbar fusion surgery.

Settings and conduct

This clinical trial was performed on 90 patients aged 20-65 years old referred to an Sari neurosurgeon clinic who needed laminectomy surgery and lumbar vertebrae fusion with pedicular screw up to 4 vertebral levels. Then, for patients, a checklist filled with demographic characteristics, smoking, occupation, type of treatment, and type of disease is filled up. Then, the radiologist will be aware of the patient's clinical picture of the MRI scan. Modic changes are reported in dominant in any disk variation. At the beginning of the study, the severity of pain was completed on the basis of the Visual Analogue Scale and the individual's ability to perform daily tasks based on the Oswestry Disability Index. The levels of vitamin D in preoperative patients are taken. According to the "random sample table", the patients are divided into 3 randomized groups of 30, including the Fusion group and the fusion group and alendronate, and the fusion group and vitamin D group. After 6 months, the lumbar magnetic resonance imaging (MRI) and clinical parameters of pain are recorded based on VAS, (ODI) in months 1, 3, and 6, and then recorded.

Participants/Inclusion and exclusion criteria

Entry criteria: Patients with degenerative diseases include lumbar spinal diskopathy, spinal stenosis, lumbar spinal listesis, requiring laminectomy and lumbar fusion with pedicles screw up to 4 vertebral levels, and surgical identification is determined by a neurosurgeon. Patients with traumatic lesions, neoplastic, infectious and the history of surgery, diabetic, disabling background and rheumatic disorders are not included in the study. People

who do not modic change in MRI are not included in the study. Patients with renal failure and GFR below 40 will not receive alendronate.

Intervention groups

Patients were divided into 3 groups of 30, including fusion (control), fusion and alendronate (interventional), fusion and vitamin D (interventional) groups. The fusion group needs laminectomy and lumbar spine sciatica with up to 4 vertebral vertebrae. The alendronate group, in addition to fusion surgery, received 70 mg oral alendronate for 6 months as an adjunct therapy every 2 weeks. In group 3, in addition to fusion surgery, 50,000 units of vitamin D are received monthly for 6 months.

Main outcome variables

Pain severity; Modic change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140915019185N2**

Registration date: **2018-02-13, 1396/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-13, 1396/11/24**

Update count: **0**

Registration date

2018-02-13, 1396/11/24

Registrant information

Name

kaveh haddadi

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1058

Email address

k.haddadi@mazums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2015-09-01, 1394/06/10

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of vitamin D and oral alendronate in patients with low back pain and modic changes who underwent lumbar fusion surgery.

Public title
The efficacy of vitamin D and oral alendronate on Modic change

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Female patients with lumbar degenerative diseases undergoing pedicular screw fusion up to 4 level

Exclusion criteria:

Patients with infection, tumor, diabetes, history of previous surgery, rheumatoid diseases

Age
From **20 years** old to **65 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomize numbers table

Blinding (investigator's opinion)
Double blinded

Blinding description
After taking surgery and treatment informed consent of patients, just patients surgeon as main project researcher will informed about the kind of drug investigation and follow up of the patients.

Placebo
Not used

Assignment
Parallel

Other design features

First study about the efficacy of 2 available oral drug on modic change

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice-chancellor of Research, Moalem Ave.

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2015-08-31, 1394/06/09

Ethics committee reference number

IR.MAZUMS.REC.94-1769

Health conditions studied

1

Description of health condition studied

Lumbar discopathy

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Spinal stenosis

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Lumbar listesis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Modic change

Timepoint

FIRS of study, 6 month after study

Method of measurement

MRI

2

Description

Pain

Timepoint

0,1,3,6

Method of measurement

Visual Analogue Scale

3

Description

Ability to do daily work

Timepoint

0,1,3,6

Method of measurement

Oswestry Disability Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: fusion and alendronate: after fusion surgery, for 6 months, 70 mg of oral alendronate is given as a treatment every 2 weeks, with the necessary training.

Category

Treatment - Surgery

2

Description

Intervention group: fusion and vitamin D: after fusion surgery, 50000 vitamin D units are received monthly for 6 months

Category

Treatment - Surgery

3

Description

Control group: fusion: needed laminectomy and lumbar fusion with a pedicular screw up to a maximum of 4 level vertebrae

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital, Mazandaran University Of Medical Science, sari, Iran

Full name of responsible person

Kaveh Haddadi

Street address

Emam Khomeini hospital, Amir Mazandarani Ave

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Email

k.haddadi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

Street address

Moalem Ave

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48157-33971

Phone

+98 11 3325 7230

Email

m.saedi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Kaveh Haddadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Kaveh Haddadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Kaveh Haddadi

Position

Associate professor

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data of the participants in the test and analysis of the test will be available upon completion of the study if patients are satisfied.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Truly working in academia and academia

Under which criteria data/document could be used

For systematic review studies and after permission from patients

From where data/document is obtainable

Kaveh Haddadi k.haddadi@mazums.ac.ir

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

After sending the email, the data will be provided to the applicant within 5 months

Comments