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

Design

The effecacy 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 scrow 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 disk opathy, spinal stenosis, lumbar spinal listesis, requiring laminectomy and lumbar fusion with pedicles scrow 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
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
+98 11 3337 0881
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
City
Sari
Province
Mazandaran
Postal code
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
Street address
Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3335 7255
Email
k.haddadi@mazums.ac.ir

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
Street address
Emam Khomeini hospital, Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1058
Fax
+98 11 3336 1058
Email
k.haddadi@mazums.ac.ir

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
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Emam Khomeini hospital, Amir Mazandarani Ave
City
sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1058
Fax
+98 11 3336 1058
Email
k.haddadi@mazums.ac.ir

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