Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of oral pantoprazole and famotidine effect on new bone formation in patients with lumbar spine fusion surgery

Protocol summary

Study aim
Comparison of the effect of oral pantoprazole and famotidine on the rate of new ossification in patients undergoing lumbar spine fusion surgery

Design
In a double-blind study on 58 patients, patients were divided into two groups of pantoprazole and famotidine in parallel based on the Block randomization method.

Settings and conduct
The aim of this study was a randomized clinical trial (RCT) with the aim of evaluating for six months the effects of pantoprazole and famotidine on the amount of bone marrow in patients undergoing lumbar fusion surgery at Imam Khomeini Hospital in Sari. The study will be registered in the clinical trial system after approval.

Participants/Inclusion and exclusion criteria
Inclusion conditions for patients with degenerative disease require lumbar fusion surgery including spinal stenosis, spondylolisthesis-deformity, discopathies of both sexes and ages 30-65 years and BMI between 20 and 35. Exclusion criteria • Patients with diabetes, patients who are heavy smokers, BMI less than 20 or more than 35, age less than 30 years or more than 65 years, patients who consent to enter Do not study, patients with a history of osteoporosis are treated

Intervention groups
pantoprazole-famotidine

Main outcome variables
Bone fusion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140915019185N4**
Registration date: **2020-11-11, 1399/08/21**
Registration timing: **registered_while_recruiting**
Last update: **2020-11-11, 1399/08/21**
Update count: **0**

Registration date
2020-11-11, 1399/08/21

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
2020-09-22, 1399/07/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of oral pantoprazole and famotidine effect on new bone formation in patients with lumbar spine fusion surgery

Public title
Comparison of oral pantoprazole and famotidine effect on new bone formation in patients with lumbar spine fusion surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with degenerative disease requiring lumbar fusion surgery for spinal canal stenosis . patients with degenerative disease requiring lumbar fusion surgery for spondylolisthesis. patients with degenerative disease requiring lumbar fusion surgery for deformity. patients with degenerative disease requiring lumbar fusion surgery including discopathies .

Exclusion criteria:

Patients with low back injury due to trauma, infection, tumor, and inflammatory diseases, including rheumatoid arthritis Patients with diabetes Patients who smoke heavily A person's BMI is less than 20 or more than 35 Patients who do not have the consent to enter the study Patients with a history of osteoporosis are treated

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

These patients are divided into two groups: pantoprazole and famotidine based on block randomization method. Both groups are treated with pantoprazole or famotidine for 8 weeks after surgery. The dose is 40 mg daily and in the morning. All patients are operated on by a surgeon. Eligible individuals will be randomly assigned to the two arms of the study in a 1: 1 ratio. The randomization method is block (Block Randomization) so that people are equally assigned to each of the two groups. In this method, we use blocks with multiple variables of two sizes (block sizes of 4 or 6) and sequence random blocks with R ndomizer package and put this sting in sealed envelopes for each person. We will give. This was done by a project epidemiologist and other members of the research team will not be aware of it.

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 Mazandaran University of Medical Sciences

Street address

Amir Mazandarani Imam Khomeini Hospital Neurosurgery Department

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1399.039

Health conditions studied

1

Description of health condition studied

spondylosis

ICD-10 code

m47

ICD-10 code description

فیکس و ثابت شدن مهره ها(اسپوندیلوز)

Primary outcomes

1

Description

Bone fusion

Timepoint

Before, three and six months after surgery

Method of measurement

Radiology and CT scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Pentoprazole at a dose of 40 mg once daily for 8 weeks orally

Category

Treatment - Drugs

2

Description

Intervention group 2: Famotidine at a dose of 40 mg once daily for 8 weeks orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Sari
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 1058
Fax
+98 11 3336 1058
Email
k.haddadi@mazums.ac.ir
Web page address
https://www.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
Fax
+98 11 3325 7230
Email
m.saedi@mazums.ac.ir
Web page address
https://www.mazums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
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
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
Fax
+98 11 3335 7255
Email
k.haddadi@mazums.ac.ir
Web page address
https://www.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
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
Web page address
https://www.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
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
Web page address
https://www.mazums.ac.ir/

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