

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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

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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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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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