

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study on the effect of vitamin D 3 + Erythropoietin + Pentoxifylline and normal saline on the improvement of patients candidate for lumbar or neck laminectomy of Imam Reza Hospital in Kermanshah (2018-2019)

Protocol summary

Study aim

A comparative study on the effect of vitamin D 3 + Erythropoietin + Pentoxifylline and normal saline on the improvement of patients candidate for lumbar or neck laminectomy

Design

This study is a double-blind clinical trial. The study population will be included all patients that will be admitted to Imam Reza hospital in Kermanshah city. 60 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza hospital of Kermanshah city, is double-blinded, in this way, participants and researchers will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for elective laminectomy; Age 20 to 70 years; Class I, II ASA patients
Exclusion criteria: Hemodynamic instability; Major disorders of the liver, kidney, or cardiovascular system, in particular, the atrial block; The experience of previous treatment with calcium channel blockers
Drug use; Patients with coagulation disorders and emergency surgery

Intervention groups

The intervention group will receive pearl vitamin D3 with a dose of 50,000 units in a single dose a day before surgery + Erythropoietin 40000 units are given as a single dose one hour before surgery + Pentoxifylline pills with the dose of 400 mg one day before surgery. The control group before the start of surgery will receive normal saline 9.0 %.

Main outcome variables

Quality of life, functional disability, pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N93**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-19, 1395/03/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of vitamin D 3 + Erythropoietin + Pentoxifylline and normal saline on the improvement of patients candidate for lumbar or neck laminectomy of Imam Reza Hospital in Kermanshah (2018-2019)

Public title

The comparison of the effect of vitamin D 3 + Erythropoietin + Pentoxifylline and normal saline on the improvement of patients candidate for lumbar or neck laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients are candidates for elective laminectomy Age 20 to 70 years Class I, II ASA patients

Exclusion criteria:

Hemodynamic instability Major disorders of the liver, kidney, or cardiovascular system, in particular, the atrial block The experience of previous treatment with calcium channel blockers Drug use Patients with coagulation disorders and emergency surgery

AgeFrom **20 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomly Individually by random number table through of receive code

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, researchers, and data analyst will keep blinded to the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

ir.kums.rec.1396.707

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

Laminectomy

ICD-10 code

M99

ICD-10 code description

vertebral column

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

Quality of Life

Timepoint

After surgery and three months after surgery

Method of measurement

Using Quality of Life Questionnaire (SF-36)

2**Description**

Functional disability

Timepoint

After surgery and three months after surgery

Method of measurement

Using Oswestry Disability Index

3**Description**

Intensity of pain

Timepoint

After surgery and three months after surgery

Method of measurement

Using Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive pearl vitamin D3 with a dose of 50,000 units in a single dose a day before surgery+Erythropoietin 40000 units are given as a single dose one hour before surgery+Pentoxifylline pills with the dose of 400 mg one day before surgery.

Category

Treatment - Drugs

2

Description

Control group will receive normal saline

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Vahid bavandpour

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Dr_v_b2018@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Vahid Bavandpour

Position

Resident of neurosurgery

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

En In a 30-day period, the documents will be sent e-mail

Comments