Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of gabapentin with and without high doses of vitamin C on the reduction of morphine consumption after lumbar disc surgery

Protocol summary

Study aim
A comparative study of the effect of gabapentin with and without high doses of vitamin C on the reduction of morphine consumption after lumbar disc surgery

Design
This study is one-blinded clinical trial.The study population will included all patients with spinal surgery who referred to Imam Reza hospital of Kermanshah city.100 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

Settings and conduct
This study that will be conducted in Imam Reza hospital of Kermanshah city is one-blinded one in this way that Clinical caregiver will be unaware of participants coding and the dose of the drug that groups will receive.To measure the severity of the pain, a ruler is marked that 0 is the sign of lack of pain and 10 is the sign of severe pain that is experienced by the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients undergoing spinal surgery
Exclusion criteria:Patients with narcotic allergies; History of alcohol and drug abuse; History of seizure;Psychopathy

Intervention groups
The first intervention group will received two grams of vitamin C before injection. The second intervention group will received 400 mg of gabatanin intravenously

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N119**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **prospective**

Last update: **2019-04-22, 1398/02/02**
Update count: **0**

Registration date
2019-04-22, 1398/02/02

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-10, 1398/02/20

Expected recruitment end date
2019-08-11, 1398/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of gabapentin with and without high doses of vitamin C on the reduction of morphine consumption after lumbar disc surgery

Public title
Comparison of the effect of gabapentin with and without high doses of vitamin C on the reduction of morphine consumption after lumbar disc surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing spinal surgery
Exclusion criteria:
Patients with narcotic allergies History of alcohol and drug abuse History of gabapentin allergy Use of analgesics 48 hours before surgery History of seizure Psychopathy
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomly Individually by random number table via code receipt
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, Clinical caregiver will be kept blind to study groups, the dosage of the drug and manufacturer of the drug. In this way,the clinicians are unaware of participants coding and the dose of the drug that groups will receive
Placebo
Not 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
2019-01-30, 1397/11/10
Ethics committee reference number
ir.kums.rec.1398.040

Health conditions studied

1

Description of health condition studied
Lumbar Disk Herniation
ICD-10 code
G55.1*
ICD-10 code description
Nerve root and plexus compressions in intervertebral disc disorders

Primary outcomes

1

Description
Pain
Timepoint
Immediately after surgery, 48, 36, 24, 12, 6, 2, and 1 hour after surgery
Method of measurement
Using the ruler degree

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will received two grams of vitamin C before injection.
Category
Treatment - Drugs

2

Description
The second intervention group will received 400 mg of gabatanin intravenously
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Emam Reza Hospital, Parastar Boulevard
Full name of responsible person
Peyman Heyrati
Street address
Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Peyman Heyrati
Position
Resident of Anesthesia
Latest degree
Medical doctor
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Anesthesiology
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
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
3 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
In a 35-day period, the documents will be sent e-mail
Comments