

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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 include 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 receive two grams of vitamin C before injection. The second intervention group will receive 400 mg of gabapentin 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)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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 gabapentin 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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

Pheyрати@yahoo.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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3836 0014

**Email**

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

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

Pheyрати@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Hassanali Karimpour

**Position**

Faculty Member of Kermanshah University of Medical  
Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

ha\_karimpour@kums.ac.ir

## Person responsible for updating data

**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

**Other areas of specialty/work**

Anesthesiology

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**City**

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**Postal code**

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**Phone**

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**Email**

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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**