

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of preoperative use of oral gabapentin and pregabalin on spinal anesthesia characteristics and side effects

Protocol summary

Study aim

Determination of the effect of preoperative oral gabapentin and pregabalin on the characteristics and complications of spinal anesthesia

Design

This study is a clinical trial with parallel groups, randomized, phase one on 72 patients. For randomization in this study, permuted block randomization is performed with hexagonal blocks of letters A, B and C and two each (15 blocks), each of them will be labeled by codes 1 to 15 and then using the table of random numbers numbers 1 to 15 will be selected and finally a sequence of letters A, B and C will be created.

Settings and conduct

This study is a double-blind clinical trial in which the clinical caregiver and participants were kept blind. The study was performed at Shahid Beheshti Hospital in Kashan in 2018-2019.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 18-70 years with ASA CLASS1-2 who undergo orthopedic or urological elective surgery below the T10 level under spinal anesthesia and their surgery time is less than 2 hours. Exclusion criteria: weight less than 40 kg, hypersensitivity to pregabalin, allergy to gabapentin or bupivacaine, localized sepsis at the injection site, dissatisfaction with spinal anesthesia

Intervention groups

Intervention group 1: receive 300 mg of oral gabapentin, Intervention group 2: receive 150 mg of oral pregabalin. Control group: receive an oral placebo (with the same drug form, appearance, and color similar to gabapentin and pregabalin containing the ineffective drug) 2 hours before surgery.

Main outcome variables

Time of onset of sensory block, duration of anesthesia, postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200918048748N1**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **retrospective**

Last update: **2020-11-02, 1399/08/12**

Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Nilofar barzegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5550 0111

Email address

n.barzegar87@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-24, 1398/04/03

Expected recruitment end date

2019-11-07, 1398/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of preoperative use of oral gabapentin and pregabalin on spinal anesthesia characteristics and side effects	
Public title	Comparison of the effect of gabapentin and oral pregabalin on spinal anesthesia
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Being at the age of 18-70 years ASA class 1-2 undergoing orthopedic elective surgery with spinal anesthesia below the T10 level Duration of surgery less than 2 hours
Exclusion criteria:	Weight less than 40 kg Hypersensitivity to pregabalin Hypersensitivity to the drug gabapentin Allergy to bupivacaine Localized sepsis at the injection site of the spinal needle Pregnancy and lactation
Age	From 18 years old to 70 years old
Gender	Both
Phase	2-3
Groups that have been masked	No information
Sample size	Target sample size: 72
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization in this study is done as permuted block randomization with hexagonal blocks of letters A, B and C and two of each (15 blocks), each of them will be labeled by codes 1 to 15 and then using the table of random numbers numbers 1 to 15 will be selected and finally a sequence of letters A, B and C will be created. The letters represent each of the study groups and after entering the study, patients receive one of the medications prescribed by the nurse. The drugs are prepared in the same containers and in the form of capsules with the same and uniform pustules. The person prescribing the medication is different from the person filling out the checklist.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Kashan University of Medical Sciences
Street address	Kashan University of Medical Sciences; Parstar boulevard; Qutb Ravandi boulevard
City	Kashan
Province	Isfahan
Postal code	8739118631
Approval date	2019-12-01, 1398/09/10
Ethics committee reference number	IR.KAUMS.MEDNT.REC.1398.093
Health conditions studied	
<u>1</u>	
Description of health condition studied	Spinal anesthesia
ICD-10 code	O89.4
ICD-10 code description	Spinal and epidural anesthesia-induced headache during the puerperium
Primary outcomes	
<u>1</u>	
Description	Sensory block start time
Timepoint	It is measured and recorded every 5 minutes until the end of the operation and every 15 minutes in recovery for up to two hours.
Method of measurement	Based on the Visual Analogue Scale and recorded in the checklist.
<u>2</u>	
Description	Duration of anesthesia
Timepoint	It is measured and recorded every 5 minutes until the end of the operation and every 15 minutes in recovery for up to two hours.
Method of measurement	Based on the Visual Analogue Scale and recorded in the checklist.
<u>3</u>	
Description	Postoperative nausea and vomiting
Timepoint	

They are measured and recorded every 5 minutes until the end of the operation and every 15 minutes in recovery for up to two hours.

Method of measurement

The incidence and severity of postoperative nausea and vomiting are assessed based on the simplified criterion of postoperative nausea and vomiting (PONV scale).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A with 300 mg of oral gabapentin made in Iran and Abidi Pharmaceutical Company, Patients receive this substance 2 hours before surgery. In sterile conditions after skin anesthesia with 2 CC lidocaine 2%, spinal anesthesia using cutting needle 25 and through the space between L5-L4 and L3-L4 vertebrae in The midline is performed with 15 mg of 0.5% hyperbaric bupivacaine for patients.

Category

Treatment - Drugs

2

Description

Intervention group: Group B, 150 mg Pregabalin made in Iran and Abidi Pharmaceutical Company, Patients receive this substance 2 hours before surgery. In sterile conditions after skin anesthesia with 2 CC lidocaine 2%, spinal anesthesia using cutting needle 25 and through the space between L4-L5 and L3-L4 vertebrae in The midline is performed with 15 mg of 0.5% hyperbaric Bupivacaine for patients.

Category

Treatment - Drugs

3

Description

Control group: Group C Oral placebo, Placebo capsule made in Iran and Abidi Pharmaceutical Company, Patients receive this substance 2 hours before surgery. In sterile conditions after skin anesthesia with 2 CC lidocaine 2%, spinal anesthesia using cutting needle 25 and through the space between L4-L5 and L3-L4 vertebrae in The midline is performed with 15 mg of 0.5% hyperbaric Bupivacaine for patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Niloofer Barzegar

Street address

Kashan University of Medical Sciences; Parstar boulevard; Qutb Ravandi boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

Kashan University of Medical Sciences
Full name of responsible person
 Niloofar Barzegar
Position
 Assistant
Latest degree
 Medical doctor
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)

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

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access period starts from 2020-2021

To whom data/document is available

Researchers

Under which criteria data/document could be used

For application or additional studies

From where data/document is obtainable

Send mail to n.barzegar87@gmail.com

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

Request in person or by e-mail

Comments