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)

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+98 31 5550 0111

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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

1

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
Isfehan
Postal code
8739118631
Approval date
2019-12-01, 1398/09/10
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.093

Health conditions studied

1

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

1

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.

2

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.

3

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

Niloofar Barzegar

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

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Sponsors / Funding sources

1

Sponsor

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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
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
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