Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of prophylactic effect of gabapentin on intrathecal fentanyl-induced pruritus in orthopedic patients

Protocol summary

Summary

With the aim of evaluating prophylactic effect of oral gabapentin on intrathecal opioid-induced pruritus and after obtaining approval from Emam Khomeini research board and ethics committee of Urmia University Of Medical Sciences, 80 male and female patients with class I-II American Society of Anesthesiologist (ASA) aged 20-50 scheduled for elective lower limb orthopedic surgery under spinal anesthesia will be enrolled in the study. Patients with any contraindication of spinal anesthesia; any pruritus before surgery; known history of allergy to gabapentin; morbid obesity; history of skin disease and any systemic disorder accompanying pruritus will be excluded from the study. The patients with be allocated to study and placebo groups using random allocation software. The study and placebo group patients will receive 600 milligram oral gabapentin and placebo two hours before induction of anesthesia respectively. In the operating room, IV cannula will be inserted and standard monitoring including blood pressure, EKG and pulse oximetry will be attached to all the patients. Then 5 cc/Kg Ringer solution will be infused. Spinal anesthesia will be induced using 12 milligrams 0.5 % hyperbaric bupivacaine and 30 microgram fentanyl in a sterile manner and the time of injection will be recorded. One hour after intrathecal injection, the patients will be asked about the feeling of pruritus, its locations and severity, and nausea and vomiting. As occurrence, nausea and vomiting will be managed with 8 mg dexamethasone and 10 mg metoclopramide intravenously. Again, the patients will be evaluated at hours 6, 12 and 24 following intrathecal injection and will be evaluated about aforementioned complaints and will be managed accordingly as occurrence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017033025600N4**
Registration date: **2017-05-21, 1396/02/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Shahram Shokohi

Name of organization / entity

Urmia University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 8967

Email address

shokohi.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Urmia University Of Medical Sciences

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic effect of gabapentin on intrathecal fentanyl-induced pruritus in orthopedic

patients

Public title
The effect of gabapentin on intrathecal opioid-induced pruritus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: male and female patients with class I-II American Society of Anesthesiologist (ASA) aged 20-50 scheduled for elective lower limb orthopedic surgery under spinal anesthesia Exclusion criteria: any contraindication of spinal anesthesia; any pruritus before surgery; known history of allergy to gabapentin; morbid obesity; history of skin disease and any systemic disorder accompanying pruritus
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In an attempt to achieve a higher standard of scientific rigor, the study has planned as a double-blind experiment. By using this, biases carried by and experiment's subject and researcher will be eliminated. Regarding the probability of conscious and unconscious biases, the study is planned as a double-blind placebo-controlled clinical trial research.In these double-blind experiments, neither the participants nor the researchers know which participants belong to the control group, nor the test group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University Of Medical Sciences
Street address
Urgence street,Resaalat boulevard
City
Urmia
Postal code
Approval date
2016-10-26, 1395/08/05
Ethics committee reference number
IR.umsu.rec.1395.302

Health conditions studied

1

Description of health condition studied
Intrathecal opioid-induced pruritus
ICD-10 code
Y45.0
ICD-10 code description
Opioids and related analgesics

Primary outcomes

1

Description
Intrathecal fentanyl-induced pruritus
Timepoint
At hours 1, 6, 12 and 24 after intratethcal fentanly injection
Method of measurement
Check list

Secondary outcomes

empty

Intervention groups

1

Description
600 milligram oral gabapentin, 2 hours before intrathecal fentanyl injection
Category
Treatment - Drugs

2

Description
Oral placebo 2 hours before intrathecal fentanyl injection
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Emam Khomeini teaching hospital
Full name of responsible person
Dr. Shahram Shokohi
Street address

Department of anesthesiology, Ershad street, Modarres boulevard

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of resrearch, Urmia University Of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urgence avenue, Jahad street, Resalat boulevard

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of resrearch, Urmia University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia University Of Medical Sciences

Full name of responsible person

Dr. Shahram Shokohi

Position

Assistant professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty