

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 will 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 fentanyl 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 resresearch, 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 resresearch, 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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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