

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Assessment of Gabapentin effect on postoperative pain, nausea, and vomiting in patients undergoing laparoscopic urology surgery

Protocol summary

Registration timing: **prospective**

Study aim

Assessment of Gabapentin effect on postoperative pain, nausea, and vomiting in patients undergoing laparoscopic urology surgery

Last update: **2022-05-27, 1401/03/06**

Update count: **0**

Registration date

2022-05-27, 1401/03/06

Design

A double-blind, randomized clinical trial study with parallel groups and phases 3 on 42 patients. Randomization will be done with the block randomization method using Random allocation software.

Registrant information

Name

Saman Farshid

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

This study will be conducted on candidate patients for laparoscopic urology in Urmia Imam Khomeini Hospital. This study will be a double-blind study and the patient and the researcher who will evaluate the outcomes will be blinded to the allocation of patients into intervention or placebo groups.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

In this study, 42 patients candidates for laparoscopic urology surgery, the aged 18 to 65 years, and class ASA I and II will be included. Patients with any coagulopathy and opium addiction will be excluded.

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Patients in the intervention group will receive a number 300 mg capsule of gabapentin 2 hours before surgery and a number 300 mg capsule daily until 48 hours after surgery (each patient will receive a total of three capsules). In the placebo group, they will receive the same number of placebo capsules.

Main outcome variables

The primary outcomes will include pain, nausea, and vomiting after surgery.

Scientific title

Assessment of Gabapentin effect on postoperative pain, nausea, and vomiting in patients undergoing laparoscopic urology surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180625040232N9**

Registration date: **2022-05-27, 1401/03/06**

Public title

Assessment of Gabapentin effect in patients undergoing laparoscopic urology surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for laparoscopic urology Age between 18 and 65 years Patients with physical status one and two according to the criteria of the American Anesthesia Association (ASA I, II)

Exclusion criteria:

Having any coagulopathy Opium addiction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention or placebo groups using the block randomization method based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total determined sample size will be entered, and then in the block section, the Block randomization method will be implemented. Patients will be allocated to groups based on generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blind to the allocation of patients into intervention or placebo groups. Placebo capsules will be similar in shape and size to gabapentin capsules. Gabapentin and placebo capsules will be coded A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini University

hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.013

Health conditions studied

1

Description of health condition studied

laparoscopic urology

ICD-10 code

PK80.6

ICD-10 code description

Urological procedure associated with injury or harm in therapeutic use

Primary outcomes

1

Description

Pain

Timepoint

6, 24, 12 and 48 hours after surgery

Method of measurement

Visual analogue scale (VAS)

2

Description

Nausea and vomiting

Timepoint

6, 24, 12 and 48 hours after surgery

Method of measurement

Post operative nausea and vomiting scale (PONV scale)

Secondary outcomes

1

Description

Dosage of analgesic

Timepoint

Up to 48 hours after surgery

Method of measurement

milligram

2

Description

Receiving anti-nausea and vomiting medicine

Timepoint

Up to 48 hours after surgery

Method of measurement

yes/ no

Intervention groups**1****Description**

Intervention group: Patients in the intervention group will receive a number 300 mg capsule of gabapentin 2 hours before surgery and a number 300 mg capsule daily until 48 hours after surgery (each patient will receive a total of three capsules).

Category

Treatment - Other

2**Description**

Control group: Patients in the placebo group will receive a number 300 mg capsule of placebo 2 hours before surgery and a number 300 mg capsule daily until 48 hours after surgery.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital

Full name of responsible person

DR. Saman Farshid

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

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Urmia University of Medical Sciences, Resalat Ave,

Jahad Blvd, Urmia, Iran.

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gholizadeh.s@umsu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saman Farshid

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

The results will be published as an article and the data will not be published.

From where data/document is obtainable

Corresponding author

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

By email address of the corresponding
author:farshid.s@umsu.ac.ir

Comments