Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

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.

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.

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.

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.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180625040232N9**
Registration date: **2022-05-27, 1401/03/06**
Registration timing: **prospective**

Last update: **2022-05-27, 1401/03/06**
Update count: **0**

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

Registrant information

Name
Saman Farshid

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 9931

Email address
farshid.s@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

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
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.
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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
Street address
Urmia University of Medical Sciences, Resalat Ave, Jahad Blvd, Urmia, Iran.
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+98 44 3223 3009
Email
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
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.
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Person responsible for scientific inquiries

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Person responsible for updating data

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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