Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of preoperative administration of gababentin to prevent or reduce pain following laparoscopy of advanced endometriosis

Protocol summary

Study aim
The effect of Gababentin preoperative administration to prevent or reduce pain following laparoscopy of advanced endometriosis

Design
Clinical trial with control and intervention group, three blind strains, phase 3 on 140 patients with 70 patients in each group

Settings and conduct
This study was performed in women with endometriosis referred to Hazrat Rasool Akram Hospital in 1300-1400. 70 patients with endometriosis will be in the gabapentin treatment group and 70 patients with endometriosis will be in the control group. Written consent to participate in the study is obtained. Then, in the treatment group, 600 mg of gabapentin with 30 cc of water is given one hour before the operation, and in the control group, placebo is given that have the same packaging and color. Patients All patients involved in this study, including surgeons and anesthesiologists and nurses, are not aware of the type of drug given to the patient. All patients undergo general anesthesia and laryngeal intubation. The operation time and operation technique are the same for all patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with endometriosis aged 16-40 years in Stage 3 and 4 diseases. Exclusion criteria: Kidney and liver patients, patients with gabapentin allergy, patients with mental disorders and epilepsy, as well as patients who have taken painkillers and any drugs and cigarettes one week before surgery

Intervention groups
70 patients with endometriosis will be in the gabapentin treatment group and 70 patients with endometriosis will be in the control group. Then, in the treatment group, 600 mg of gabapentin with 30 cc of water is given one hour before the operation, and in the control group, placebo is given that have the same packaging and color.

Main outcome variables
Reducing pain and reducing postoperative drug use using a single dose of gabapentin before surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150817023666N14**
Registration date: **2021-04-21, 1400/02/01**
Registration timing: **prospective**

Last update: **2021-04-21, 1400/02/01**
Update count: **0**

Registration date
2021-04-21, 1400/02/01

Registrant information

Name
Abolfazl Mehdizadeh kashi

Name of organization / entity
Iran University of Medical Science

Country
Iran (Islamic Republic of)

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+98 216651500

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mehdizadeh.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative administration of gababentin to prevent or reduce pain following laparoscopy of advanced endometriosis

Public title

Evaluation of the effect of gabapentin in reducing pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Endometriosis patients aged 16-40 years in Stage 3 and 4 diseases

Exclusion criteria:

Kidney and liver patients patients with gabapentin allergy patients with mental disorders and epilepsy patients who have taken painkillers and any drugs and cigarettes one week before surgery

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in this study is limited to intervention and placebo groups using randomization. Random allocation law is the simplest and most limited method of randomization. This method represents a large block for the entire sample volume. For this purpose, the researchers first determined a total sample size, then randomly assigned a set of them to group A and the remainder to group B. For example in this study. A sample of 140 balls, 70 balls for intervention group A and 70 balls for intervention group B, was placed in a lottery container and then the balls were randomly removed from the container and replaced. This method is used for two or more group experiments.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The participant, the treating physician, the data collector, and the data analyzer are blind to the type of drug (drug and placebo). Randomization will be performed using a computer program. The codes are randomly selected for each participant. Each patient has a unique code. Based on the coding on the drug, the lead researcher will provide the drug to the participant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Sattarkhan . Niayesh Street. Rasool Akram Hospital

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.IUMS.REC.1399.1354

Health conditions studied

1

Description of health condition studied

Reduction of pain after laparoscopic endometriosis surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction of pain and drug use after laparoscopic surgery

Timepoint

6, 12 and 24 hours after surgery

Method of measurement

Pain questionnaire based on Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, 600 mg of gabapentin with 30 cc of water is given to the patient one hour before the operation.
Category
Treatment - Drugs

2

Description
Control group: In the control group, an hour before the operation is given a placebo that has the same packaging and color
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Abolfazl Mehdizadeh Kashi
Street address
Sattar Khan. Niayesh Street. Rasool Akram Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Abbas Motevalian-Vice President for Research of Iran University of Medical Sciences
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Abolfazl Mehdizadeh Kashi
Position
Professor of Laparoscopic Surgery
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available