

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

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

#### Study aim

The effect of Gabapentin 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

#### 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)

##### Phone

+98 216651500

##### Email address

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 gabapentin 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

mehdizadeh.a@iums.ac.ir

## 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

##### Street address

Sattar Khan. Niayesh Street. Rasool Akram Hospital

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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

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

#### Contact

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Iran University of Medical Sciences

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## Person responsible for updating data

### 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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## 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