

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Effect of oral gabapentin versus placebo on pain relief after gynecologic surgery: a triple blinded randomized clinical trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of oral gabapentin versus placebo on pain relief after gynecologic surgery.

**Design:** A triple blinded randomized clinical trial. Setting and conduct: All eligible patients candidate for gynecologic surgery with hypogastric incision (hysterectomy, myomectomy, and ovarian cyst) who will refer to clinic of Besat Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) age of 18 to 65 years; (b) women with physical class ASA I-II; (c) candidate for elective gynecologic surgery. Exclusion criteria: (a) contraindication for neuroaxial anesthesia; (b) history of hypertension or diabetes mellitus; (c) using narcotics or psychotropic. Intervention: (a) 34 patients will receive two gabapentin capsules 300 mg (600 mg) single dose 2 hours before surgery; (b) 34 patients will receive one gabapentin capsule 300 mg plus one placebo capsule (containing starch) single dose 2 hours before surgery. Control: 34 patients will receive two placebo capsules (containing starch) single dose 2 hours before surgery. Primary outcome: (a) pain severity at surgical site at 1, 6, 12, 18, 24, and 48 hours after surgery using VAS scale; (b) the amount of narcotic used during the first 48 hours after surgery per mg; (c) the duration of time to receive narcotic the first narcotic during the first 48 hours after surgery per min. Secondary outcome: (a) vertigo at 1, 6, 12, 18, 24, and 48 hours after surgery by question; (b) nausea and vomiting at 1, 6, 12, 18, 24, and 48 hours after surgery by question; (c) pruritus at 1, 6, 12, 18, 24, and 48 hours after surgery by question.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201402289014N28**

Registration date: **2014-05-26, 1393/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-26, 1393/03/05

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-06-21, 1394/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of oral gabapentin versus placebo on pain relief after gynecologic surgery: a triple blinded randomized clinical trial

##### Public title

Effect of oral gabapentin versus placebo on pain relief

after gynecologic surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: (a) age of 18 to 65 years; (b) women with physical class ASA I-II; (c) candidate for elective gynecologic surgery. Exclusion criteria: (a) contraindication for neuroaxial anesthesia; (b) history of hypertension or diabetes mellitus; (c) using narcotics or psychotropic.

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **102**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Randomization: The patients will be assign randomly to one the three trial groups using balance block randomization with the block of six. Blinding: The patients will receive capsules with the same shape but different content (gabapentin or starch), thus, they will not aware of the intervention. In addition, the physician who will examine the patients and the analyzer who will perform the data analysis will not aware of the intervention. Therefore, the study will be run triple blinded.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

**Street address**

Vice-chancellor of Research the Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

6517838695

**Approval date**

2014-05-17, 1393/02/27

**Ethics committee reference number**

P/16/35/9/711

**Health conditions studied****1****Description of health condition studied**

Pain at surgical site at inguinal area

**ICD-10 code**

R10.3

**ICD-10 code description**

Pain localized to other parts of lower abdomen

**Primary outcomes****1****Description**

Pain at the surgical site

**Timepoint**

at 1, 6, 12, 18, 24, and 48 hours after surgery

**Method of measurement**

using VAS scale

**2****Description**

the amount of narcotic used

**Timepoint**

during the first 48 hours after surgery

**Method of measurement**

per mg

**3****Description**

the duration of time to receive narcotic

**Timepoint**

during the first 48 hours after surgery

**Method of measurement**

per min

**Secondary outcomes****1****Description**

vertigo

**Timepoint**

at 1, 6, 12, 18, 24, and 48 hours after surgery

**Method of measurement**

by question

**2****Description**

nausea and vomiting

**Timepoint**

at 1, 6, 12, 18, 24, and 48 hours after surgery

## Method of measurement

by question

### 3

#### Description

pruritus

#### Timepoint

at 1, 6, 12, 18, 24, and 48 hours after surgery

#### Method of measurement

by question

## Intervention groups

### 1

#### Description

34 patients will receive two gabapentin capsules 300 mg (600 mg) single dose 2 hours before surgery

#### Category

Treatment - Drugs

### 2

#### Description

34 patients will receive one gabapentin capsule 300 mg plus one placebo capsule (containing starch) single dose 2 hours before surgery

#### Category

Treatment - Drugs

### 3

#### Description

34 patients will receive two placebo capsules (containing starch) single dose 2 hours before surgery

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beasat Hospital

##### Full name of responsible person

Dr Parisa Shirzad

##### Street address

Beasat Hospital, Shahed Square

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

#### Street address

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice-chancellor for Research the Technology, Hamadan  
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

Beasat Hospital

##### Full name of responsible person

Dr Parisa Shirzad

##### Position

Resident of Anesthesiology

##### Other areas of specialty/work

##### Street address

Beasat Hospital, Shahed Square

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##### Phone

+98 81 1341 6392

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shirzad.parisa7@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Beasat Hospital

##### Full name of responsible person

Dr Seyyed Mohammad Zolhavarieh

##### Position

Anesthesiologist

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**Person responsible for updating data**

**Contact**

**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*