

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effects of single dose of gabapentin on postoperative pain, nausea and vomiting after abdominal hysterectomy: A double blind randomized clinical trial

#### Protocol summary

##### Summary

We designed the present study to investigate whether pre-emptive use of gabapentin 300 mg orally could reduce postoperative pain, nausea and vomiting after hysterectomy. A total of 140 patients whom were candidate for elective abdominal hysterectomy randomly assigned to one of two groups according to the method of treatment: gabapentin or placebo in a double-blind manner before hysterectomy. The inclusion criteria were ASA class I and II, nonmalignant status (benign gynecologic disease), general anesthesia, and body mass index (BMI) of 20 to 30 kg/m<sup>2</sup>. The exclusion criteria were known allergy against gabapentin, motion sickness, psychiatric disorder, substance abuse, duration of surgery excess 3 hours. Gabpentin or placebo is given to patients about 1 hour before induction of anesthesia. Postoperatively, the pain was assessed on a visual analogue scale (VAS) at 1, 4, 8, 12 and 24 hours at rest. Acetaminophen intravenously was used to treat postoperative pain on VAS score. Total acetaminophen and anti emetic drug consumption in the first 24 hours after surgery was also recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404158151N6**  
Registration date: **2014-05-20, 1393/02/30**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-05-20, 1393/02/30

##### Registrant information

##### Name

Ladan Ajori

##### Name of organization / entity

Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 1694

##### Email address

ajori@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Science

##### Expected recruitment start date

2013-12-14, 1392/09/23

##### Expected recruitment end date

2014-12-14, 1393/09/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of single dose of gabapentin on postoperative pain, nausea and vomiting after abdominal hysterectomy: A double blind randomized clinical trial

##### Public title

Effects of gabapentin on postoperative pain, nausea and vomiting after hysterectomy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

All patients whom were candidate for abdominal hysterectomy assessed for eligibility to enter the study.

The inclusion criteria: ASA class I and II; nonmalignant status (benign gynecologic disease); general anesthesia; body mass index (BMI) of 20 to 30 kg/m<sup>2</sup> The exclusion criteria: known allergy against gabapentin; epilepsy; motion sickness; previous treatment with gabapentin; chronic pain syndrome; psychiatric disorder and substance abuse; patients who had received analgesics within 48 hours before surgery; duration of surgery excess 3 hours; trauma of urinary system or bowel within surgery

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shahid Beheshti University of Medical Science

**Street address**

Shohada Hospital, Tajrish Square, Valiasr Avenue

**City**

Tehran

**Postal code**

10/9/92

**Approval date**

2013-12-01, 1392/09/10

**Ethics committee reference number**

1392-1-136-1157

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

Effects of gabapentin on postoperative pain

**ICD-10 code**

N99.9

**ICD-10 code description**

Postprocedural disorder of genitourinary system, unspecified

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

postoperative pain

**Timepoint**

1 - 4 -8 -12 -24 hours post operation

**Method of measurement**

questionare, VAS score

**2****Description**

postoperative nausea and vomiting

**Timepoint**

within 24 hours post hysterectomy

**Method of measurement**

questionare

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

side effects of gabapentin

**Timepoint**

within 24 hours post hysterectomy

**Method of measurement**

Patient complanit and physical exam

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

1 hour before induction of anesthesia 1 capsules of gabapentin (300mg) were given to patient by a physician

**Category**

Treatment - Drugs

**2****Description**

in control group 1 capsules of placebo similar in shape and size with true drug were given to patient 1 hour before operation by a physician

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Shohada Tajrish hospital

**Full name of responsible person**

Leila Nazari

**Street address**

Shohada Tajrish Hospital, Tajrish square, Valiasr Avenue

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Seyyed Jalaledin Khoshnevis

**Street address**

Shohada Hospital, Tajrish Square, Valiasr Avenue

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Science

**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**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Leila Nazari

**Position**

Assisted Professor of Gynecology

**Other areas of specialty/work**

**Street address**

Shohada Tajrish Hospital, Tajrish square, Valiasr Avenue

**City**

Tehran

**Postal code**

**Phone**

+98 21 2271 8005

**Fax**

**Email**

leynaz@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Ladan Ajori

**Position**

Associated of professor

**Other areas of specialty/work**

**Street address**

Shohada hospital, Tajrish Square, Valiasr Avenue

**City**

Tehran

**Postal code**

**Phone**

+98 21 2271 8005

**Fax**

**Email**

leynaz@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Leila Nazari

**Position**

Assisted Professor of Gynecology

**Other areas of specialty/work**

**Street address**

Shohada Tajrish Hospital, Tajrish square, Valiasr Avenue

**City**

Tehran

**Postal code**

**Phone**

+98 21 2271 8006

**Fax**

**Email**

leynaz@yahoo.com

**Web page address**

**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*

