# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jun 2026

## The effects of preoperative administration of oral gabapentin on postoperative pain after abdominal hysterectomy

## Protocol summary

**Summary**

The purpose of this study was to evaluate the effects of preoperative administration of oral gabapentin on postoperative pain after surgery in the women undergoing general anesthesia for abdominal hysterectomy in Shahid Sadoughi hospital in Yazd, Iran. In this randomized double blind trial, 60 women, aged 40-60 years old, and ASA physical status I and II, were assigned into one of the following two groups to receive gabapentin, 100 microgram the night before and then 300 microgram 2 hours before surgery, orally in the intervention group or placebo in the control group. Pain was assessed through visual analog scale (VAS) at 1, 6, 12, and 24 hours after the surgery. In addition, the first request of the patient for analgesia, the amount of morphine consumed, and side effects of gabapentin (dizziness, blurred vision, tremor, ataxia, nistagmus, nausea, vomiting) were evaluated during 24 hours and compared between groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138810122963N1**
Registration date: **2011-04-23, 1390/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-04-23, 1390/02/03

**Registrant information**

**Name**
Shekoufeh Behdad
**Name of organization / entity**
Shahid Sadoughi University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Shahid Sadoughi University of Medical Sciences

**Expected recruitment start date**

2010-08-23, 1389/06/01

**Expected recruitment end date**

2011-04-21, 1390/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of preoperative administration of oral gabapentin on postoperative pain after abdominal hysterectomy

**Public title**

Evaluation of the effects of preoperative administration of oral gabapentin on postoperative pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: women with American Society of Anesthesia (ASA) physical status I or II who are candidate for elective abdominal hysterectomy, age 40-60 years old, BMI Exclusion criteria: Anaphylaxis reaction to the anesthetic drugs, duration of the operation longer than 2 hours

**Age**

From **40 years** old to **60 years** old

**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**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 Sadoughi University of Medical Sciences
**Street address**
Bahonar square
**City**
Yazd
**Postal code**
**Approval date**
2010-02-17, 1388/11/28
**Ethics committee reference number**
107684

## Health conditions studied

### 1

**Description of health condition studied**
Gabapentin
**ICD-10 code**
Y46.6
**ICD-10 code description**
Other and unspecified antiepileptics

## Primary outcomes

### 1

**Description**
postoperative pain
**Timepoint**
1,6,12,24 hours postoperatively
**Method of measurement**
visual analog pain score

### 2

**Description**
the first request of the patient for analgesic
**Timepoint**
during 24 hours after operation
**Method of measurement**
in hours

### 3

**Description**
opioid (morphine) consumption
**Timepoint**
during 24 hours after operation
**Method of measurement**
mg morphine

## Secondary outcomes

### 1

**Description**
side effects of gabapentin (dizziness, blured vision, tremor, ataxia, nistagmus, nausea, vomitting)
**Timepoint**
1, 6, 12 and 24 hours after operation
**Method of measurement**
asking the patient, physical examination

### 2

**Description**
systolic and diastolic blood pressures
**Timepoint**
1, 6, 12 and 24 hours after operation
**Method of measurement**
In mnHg by Sphyngomanometer

### 3

**Description**
heart rates
**Timepoint**
1, 6, 12 and 24 hours after operation
**Method of measurement**
beats per minute in P/E

## Intervention groups

### 1

**Description**
gabapentin, 100 microgram, orally, the night before and then 300 microgram 2 hours before surgery
**Category**
Treatment - Drugs

**2**

**Description**
placebo at the same time
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital
**Full name of responsible person**
Dr. Shekoufeh Behdad
**Street address**
Shahid Sadoughi Hospital, Yazd, Iran
**City**
Yazd

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Sadoughi University of Medical Sciences
**Full name of responsible person**
Dr. Hasan Mozaffari
**Street address**
Bahonar square
**City**
Yazd
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Sadoughi 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**
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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)**
*empty*

**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*