

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)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

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, blurred vision, tremor, ataxia, nistagmus, nausea, vomiting)

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 mmHg 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

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shekoufeh Behdad

Position

Assistant of professor

Other areas of specialty/work

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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