

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/m². 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

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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/m² 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

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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

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

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Person responsible for scientific inquiries

Contact

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Ladan Ajori

Position

Associated of professor

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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

