Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

Gabapentin is an anticonvulsant that has been shown to be effective in the treatment of neuropathic and chronic pain. The analgesic effect of its perioperative use has not been fully elucidated. Hysterectomy is one of the most common major gynecologic surgery ,therefore we designed the present study to investigate whether pre-emptive use of gabapentin 600 mg orally could reduce postoperative pain, meperidine consumption and postoperative nausea and vomiting (PONV) in the initial 24-hours 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, epilepsy, motion sickness, chronic pain syndrome, psychiatric disorder and substance abuse, duration of surgery excess 3 hours, and trauma of urinary system or bowel within surgery. Postoperatively, the pain was assessed on a visual analogue scale (VAS) at 1, 4, 8, 12 and 24 hours at rest. Meperidine intramuscularly was used to treat postoperative pain on VAS score and patients demand. Total meperidine and anti emetic drug consumption in the first 24 hours after surgery was also recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106186829N1**
Registration date: **2011-07-04, 1390/04/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-07-04, 1390/04/13

Registrant information

Name

Masoumeh Hematyar

Name of organization / entity

Islamic Azad university Tehran medical branch

Country

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Science

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effects of gabapentin on post hysterectomy pain, nausea and vomiting

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

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Science

Street address

Velenjak, Chamran highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2008-12-01, 1387/09/11

Ethics committee reference number

89-0308-3356

Health conditions studied

1

Description of health condition studied

effect of gabapentin on post operative pain of hysterectomy

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

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

Method of measurement

questionare

Secondary outcomes

1

Description

side effects of gabapentin

Timepoint

within 24 hours post hysterectomy

Method of measurement

questionare

Intervention groups

1

Description

in control group 2 capsules of placebo similar in shape and size with true drug were given to patient 1 hour before operation by a G.P

Category

Placebo

2

Description

1 hour before induction of anesthesia 2 capsules of gabapentin (300mg) were given to patient by a G.P.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Leila Nazari
Street address
Gynecology devision, Shohada Tajrish Hospital, Tajrish square, Valiasr Avenue, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Science
Full name of responsible person
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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
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Person responsible for updating data

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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

Data Dictionary

empty