

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

Iran (Islamic Republic of)

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+98 22008052

Email address

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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 division, 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

Leila Nazari

Street address

Gynecology division, Shohada Tajrish Hospital,
Tajrish square, Valiasr Avenue, Tehran, Iran

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

Resident of gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

Leila Nazari

Position

Resident of gynecology

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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