Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison between low dose of gabapentin and diclofenac on postoperative pain in patients undergoing abdominal hysterectomy with general anesthesia

Protocol summary

Summary

The aim of this study is to compare the effect of low dose of gabapentin and diclofenac on postoperative pain in patients undergoing abdominal hysterectomy with general anesthesia. This study will be performed on 100 patients undergoing abdominal hysterectomy in Rasht Al-zahra hospital in 2012-2013. After obtaining written and informed consent women aged 35-55 years without underlying disease will be divided randomly into two groups of 50 persons. One group will be treated with 300 mg oral Gabapentin capsule and suppository placebo at 8, 16, 24 hours after surgery and another group will be treated with 100mg suppository diclofenac and oral placebo capsule at 8, 16, 24 hours after surgery. All patients will be treated by 0.5 mg/kg pethedin, after transfer to the ward. The drugs will be prescribed by nursery agent to patients. Any person who are involved as executive agents in this study, have no information about prescribed drugs. The severity of pain will be evaluated using visual analogs scale (VAS) score at 2, 4, 6, 12, 24 hours after surgery. Finally VAS score in both groups will be compared using statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111710089N2**
Registration date: **2013-05-12, 1392/02/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

Name

Roya Faraji Darkhaneh

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research – Guilan university of medical sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between low dose of gabapentin and diclofenac on postoperative pain in patients undergoing abdominal hysterectomy with general anesthesia

Public title

Comparing low dose of gabapentin and diclofenac on posthysterectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: women's age between 35-55

years, informed consent – The exclusion criteria: past history of heart, lung, kidney, GI tract, liver and psychiatric disease, raised of intra-cranial pressure, hypertension, chronic pain disorder, previous surgery, prolonged surgery (upon 2 hours), emergent hysterectomy, infection and ileus after surgery.

Age
From **35 years** old to **55 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is random and double-blind because of the main outcome (determine severity of pain) is subjective, so we will omit the psychological effect of two different drug administration with this study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Guilan University of Medical Sciences

Street address
Ethics Committee, Guilan University of Medical Sciences، Gaz Square

City
Rasht

Postal code

Approval date
2013-02-09, 1391/11/21

Ethics committee reference number
1910396402

Health conditions studied

1

Description of health condition studied
Postprocedural disorders of genitourinary system, not elsewhere classified

ICD-10 code
N99

ICD-10 code description
Postprocedural disorder of genitourinary system, unspecified

Primary outcomes

1

Description
Post-operative pain

Timepoint
2, 4, 6, 12, 24 hours after surgery.

Method of measurement
By using VAS SCORE

Secondary outcomes

1

Description
Frequency of nausea

Timepoint
2,4,6,12,24 hours after surgery.

Method of measurement
Question from patient

2

Description
Frequency of vomiting

Timepoint
2,4, 6,12, 24 hours after surgery.

Method of measurement
Question from patient

3

Description
Frequency of dizziness

Timepoint
2, 4, 6,12, 24 hours after surgery.

Method of measurement
Question from patient

4

Description
Frequency of time additive pethedin needed

Timepoint
2, 4, 6,12, 24 hours after surgery.

Method of measurement
Patient’s documents

Intervention groups

1

Description
Prescription of 100 mg rectal suppository diclofenac

(Behvazan Pharmaceutical Company) plus oral placebo capsule (Ṣobhan Pharmaceutical Company) to control group three times every eight hours .

Category

Treatment - Drugs

2

Description

Prescription of 300 mg oral gabapentin (Sobhan Pharmaceutical Company) plus rectal suppository placebo (Behvazan Pharmaceutical Company) intervention group three times every eight hours .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Guilan university of medical sciences.

Full name of responsible person

Roya Faraji darkhane

Street address

Alzahra Hospital, Namjoo Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research، Guilan University of Medical Sciences

Full name of responsible person

Abdolrasol Sobhani

Street address

Gaz Square, Vice Chancellor for research

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research، Guilan 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

Giulan University of Medical Sciences

Full name of responsible person

Faeze Fashkhami

Position

Associated professor-Guilan University of Medical Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position

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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