

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the efficacy of oral Gabapentin and Tramadol after elective abdominal hysterectomy pain in general anesthesia

Protocol summary

Summary

The purpose of this study is comparison of efficacy of oral Gabapentin with Tramadol in acute pain control after elective abdominal hysterectomy under general anesthesia. Inclusion criteria: Patients aged 35 to 55; American Society of Anesthesiologists (ASA) class 1-2 Exclusion criteria: The surgical complication leading to prolonged operation time more than 2 hours; Essential requirement to other concomitant abdominal surgery. This is a double-blind clinical trial study in one hundred twenty patients. Patient are randomly divided in to 3 groups of 40 patients are receiving Tramadol 100 mg and Gabapentin 300 mg and placebo. They are giving medicines 2 hours before surgery with 50 cc water, then Visual analogue scale (VAS) in 4, 8,12,16,20 and 24 hours are investigated and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201108677N1**

Registration date: **2014-05-13, 1393/02/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-13, 1393/02/23

Registrant information

Name

Farnoush Farzi

Name of organization / entity

Guilan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-05-09, 1393/02/19

Expected recruitment end date

2014-09-10, 1393/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of oral Gabapentin and Tramadol after elective abdominal hysterectomy pain in general anesthesia

Public title

Pain control after Hysterectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 35 to 55; American Society of Anesthesiologists (ASA) class 1-2 Exclusion criteria: The surgical complication leading to prolonged operation more than 2 hours; Essential requirement to other abdominal surgery

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 120

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

Guilan University of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

4193893345

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

1920422815

Health conditions studied

1

Description of health condition studied

The relationship between oral gabapentin and tramadol in acute pain after abdominal Hystrectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

every 4 hours up to 24 hours

Method of measurement

Visual analogous score(0-10)

2

Description

Nausea and vomiting

Timepoint

Every 4 hours up to 24 hours

Method of measurement

Nausea and vomiting score (0-4)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Gabapanten 100 mg with 50 cc water 2 hours before surgery

Category

Prevention

2

Description

Intervention 2: Tramadol 100 mg with 50 cc water 2 hours before surgery

Category

Prevention

3

Description

Intervention 3: Placebo with 50 cc water 2 hours before surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Farnoush Farzi

Street address

Namjoo street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

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
Vice chancellor for research of 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
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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