

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of oral Aprepitant and Ondansetron injection individually and combining on postoperative nausea and vomiting after Laparoscopic cholecystectomy in women using general anesthesia

Protocol summary

Summary

The aim of this study is compare the effects of Ondansetron and Aprepitant on postoperative nausea and vomiting in 18 to 50 years old female patients which have laparoscopic cholecystectomy under general anesthesia. Exclusion criteria contain catching systemic disease or to have age out of the range. The study as a double blinded clinical trial will be done on 90 patients. Concurrent with operation anti nausea drug 4mg Ondansetron IV and placebo capsule is administered 1 hour before operation. In another group Aprepitant capsule 80mg 1 hour before operation with placebo ampule during operation and in third group Aprepitant before and Ondansetron during operation is administered. Nausea and vomiting in patients will be studied in 6 and 24 hours postoperative as early and late symptoms and is recorded in questionnaire. Patients information will be classified in separate tables and will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120831302N1**

Registration date: **2017-05-17, 1396/02/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-17, 1396/02/27

Registrant information

Name

Farhang Safarnejad

Name of organization / entity

Kurdistan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice President of Research, Kurdistan University of Medical Sciences, Sanandaj, Kurdistan, Iran

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral Aprepitant and Ondansetron injection individually and combining on postoperative nausea and vomiting after Laparoscopic cholecystectomy in women using general anesthesia

Public title

The effect of oral Aprepitant and Ondansetron injection on postoperative nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women between 18 to 50 years old with ASA class 1 and 2 with at least 2 criteria of APFEL (female; nonsmoker; motion sickness or PONV history;

using opioids 100mcg fentanyl or equivalent) Exclusion criteria: women under 18 or greater than 50 years old; AA class 3 or more; cholecystectomy in other anesthesia; systemic disease like diabetes; asthma; cardiovascular; reflux, severe obesity; pregnancy; breast feeding; hepatic and renal disease; neuromuscular disease; psychotic disease; addiction; acute cholecystitis.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Kurdistan University of Medical Sciences

Street address

Pasdaran BLVD

City

Sanandaj

Postal code

6617713446

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

MUK.REC.1395.256

Health conditions studied

1

Description of health condition studied

nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

nausea and vomiting

Timepoint

6 and 24 hours after operation

Method of measurement

VAS criteria

Secondary outcomes

1

Description

hospitalization period

Timepoint

at discharge time

Method of measurement

hospitalization days

Intervention groups

1

Description

group1: Ondancetron ampule 4mg intravenous after anesthetic induction and placebo capsule 1 hour before operation

Category

Treatment - Drugs

2

Description

group 2: Aprepitant capsule 80mg 1 hour before operation and placebo ampule (normal saline) after anesthetic induction is administered

Category

Treatment - Drugs

3

Description

group 3: Aprepitant capsule 80mg 1 hour before operation and Ondansetron 4mg intravenous after anesthetic induction is administered

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospitals

Full name of responsible person

Reza Karami

Street address

Vakil Street

City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice President of Research, Kurdistan University of Medical Sciences

Full name of responsible person
Nasrin Khodamoradi

Street address
Pasdaran BLVD, Kurdistan University of Medical Sciences

City
Sanandaj

Grant name

Grant code / Reference number

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

Title of funding source
Vice President of Research, Kurdistan 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
Besat Hospital, Kurdistan University of Medical Sciences

Full name of responsible person
Reza Karami

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General Surgery Resident

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