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 wil 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

Iran (Islamic Republic of)

Phone

+98 918 171 1079

Email address

safarnejhad.s@muk.ac.ir

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 vomitting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
nausea and vomitting

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 Hospitsl

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
Position
General Surgery Resident
Other areas of specialty/work
Street address
Vakil Street
City
Sanandaj
Postal code
Phone
+98 87 3322 8925
Fax
Email
reza_karami1367@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Besat Hospital, Kurdistan University of Medical Sciences
Full name of responsible person
Farhang Ssafarnejad
Position
General Surgeon
Other areas of specialty/work
Street address
Vakil Street
City
Sanandaj
Postal code
Phone
+98 87 3322 8925
Fax
Email
safarnejhad.s@muk.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Besat Hospital, Kurdistan University of Medical Sciences
Full name of responsible person
Reza Karami
Position
General Surgery Resident
Other areas of specialty/work
Street address
Vakil Street
City
Sanandaj
Postal code
Phone
+98 87 3322 8925
Fax
Email
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