

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of prevalence of nausea and vomiting after laparoscopic cholecystectomy in case of pretreatment with Haloperidol and Ondansetron

Protocol summary

Study aim

Comparison of prevalence of nausea and vomiting after laparoscopic cholecystectomy in case of pretreatment with Haloperidol and Ondansetron

Design

Double blinded randomized clinical trial

Settings and conduct

Intervention group: patients in the group one received 0.05 mg/kg IV. Haloperidol during 5 min after induction of anesthesia. Intervention group: patients in the group two received 0.15 mg/kg IV. Ondansetron after induction of anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18--60 years old Patients undergoing laparoscopy cholecystectomy under general anesthesia Cholelithiasis Chronic cholecystitis Cholecystic polyp ASA I-II. Exclusion Criteria: Underlying medical condition that is currently not under control History of allergy to drugs or use of alcohol; Parkinson History of glaucoma Bone marrow depression Severe liver disease Obstructive bowel disease History of prostate disease History of cardiac arrhythmia History of respiratory failure or respiratory distress Taking antidepressants History of allergy to haloperidol or ondansetron Pregnancy Breast feeding patients Digestive diseases, kidney and hematology History of dizziness or motion Use an anti-nausea and vomiting agent within 24 hours before the surgery Anxiety disorders, Restlessness, loss in time and place Confusion, tremor, chills, seizure, tinnitus History of Bradycardia Reduced cardiac function Low blood pressure Surgery takes more than an hour. Opium addiction.

Intervention groups

Intervention group: patients in the group one received 0.05 mg/kg IV. Haloperidol during 5 min after induction of anesthesia. Intervention group: patients in the group two received 0.15 mg/kg IV. Ondansetron after

induction of anesthesia.

Main outcome variables

Post-operative Nausea and Vomiting, Length of stay in the recovery room and the discharge time from recovery room

General information

Reason for update

Due to several refereeing corrections at the time of registration, the expected recruitment start date has not been corrected in the last refereeing. Please, change expected recruitment start date six days later.

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N85**

Registration date: **2019-08-07, 1398/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-15, 1399/11/27**

Update count: **1**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-07, 1398/05/16

Expected recruitment end date

2019-10-03, 1398/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prevalence of nausea and vomiting after laparoscopic cholecystectomy in case of pretreatment with Haloperidol and Ondansetron

Public title

Comparison of prevalence of nausea and vomiting after laparoscopic cholecystectomy in case of pretreatment with Haloperidol and Ondansetron

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18--60 years old Patients undergoing laparoscopy cholecystectomy under general anesthesia Cholelithiasis Chronic cholecystitis Cholecystic polyp ASA I-II

Exclusion criteria:

Underlying medical condition that is currently not under control History of allergy to drugs or use of alcohol; Parkinson History of glaucoma Bone marrow depression Severe liver disease Obstructive bowel disease History of prostate disease History of cardiac arrhythmia History of respiratory failure or respiratory distress Taking antidepressants History of allergy to haloperidol or ondansetron Pregnancy Breast feeding patients Digestive diseases, kidney and hematology History of dizziness or motion Use an anti-nausea and vomiting agent within 24 hours before the surgery Anxiety disorders, Restlessness, loss in time and place Confusion, tremor, chills, seizure, tinnitus History of Bradycardia Reduced cardiac function Low blood pressure Surgery takes more than an hour. Opium addiction

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization was performed based on the 6-point perturbation block method from the Randomization.org

site and the patients were divided into two groups, one and two.

Blinding (investigator's opinion)

Double blinded

Blinding description

Syringes containing Haloperidol and Ondonestrone will be prepared by an anesthetic expert who are not aware of the study according to the randomized list .Syringes are marked with the letters A, B, respectively, and the volume of the syringe containing both drugs is achieved by the same amount of normal saline (5 cc) .Patient, anesthesiologist and research specialist have been blinded to data collection.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.SUMS.MED.REC.1396.128

Health conditions studied**1****Description of health condition studied**

Laparoscopy Cholecystectomy

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes**1****Description**

Post-operative Nausea and Vomiting
Timepoint
Every 15 min at the recovery room and every 1 hour at the ward
Method of measurement
Bellville Scoring

Secondary outcomes

1

Description
Length of stay in the recovery room and the discharge time from recovery room
Timepoint
Every 15 min at the recovery room
Method of measurement
Aldrete Score

2

Description
Patients' Satisfaction
Timepoint
At the end of the trial
Method of measurement
Likert scoring

Intervention groups

1

Description
Intervention group: patients in the group one received 0.05 mg/kg IV. Haloperidol during 5 min after induction of anesthesia
Category
Prevention

2

Description
Intervention group: patients in the group two received 0.15 mg/kg IV. Ondansetron after induction of anesthesia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi Hospital
Full name of responsible person
Elisa Ramedani
Street address
Zand Street, Faghihi Hospital
City
Shiraz
Province

Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
Darman@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
sacrc@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Elisa Ramedani
Position
Physician/anesthesiology Resident
Latest degree
Medical doctor
Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

ramedani1363@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali Karami

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

alk1380@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available