Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

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

Protocol summary

Study aim
Comparison of prevalence of nausea and vomiting after laparascopic 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. Ondansetrone 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. Ondansetrone 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)
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+98 71 3647 4270
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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 laparascopic cholecystectomy in case of pretreatment with Haloperidol and Ondansetron

Public title
Comparison of prevalence of nausea and vomiting after laparascopic 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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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. Ondansetrone 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

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7134844119

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+98 71 3647 4270

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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

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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

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

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Anesthesiology Department, Faghihi Hospital, Zand Street

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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

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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

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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