Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of droperidol and granisetron with dexamethasone and granisetron in the control of postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison of droperidol and granisetron with dexamethasone and granisetron in the control of postoperative nausea and vomiting in laparoscopic cholecystectomy

Design
The study will be double blind and clinical trial.120 patients will be randomly divide into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients undergoing laparoscopic cholecystectomy at Vali-e-Asr Hospital in Arak will be randomly allocated into 3 groups using simple randomization with an envelope system. This is a double-blind study, ensuring blinding of the outcome assessor, data analyst, and participants.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:patients scheduled for laparoscopic cholecystectomy surgery, patients classified as ASA I or II, absence of renal, hepatic, or cardiovascular diseases,no history of drug abuse, alcohol consumption, or chronic use of analgesics, no history of malignancy, no history of psychiatric or psychotic disorders Exclusion Criteria: withdrawal of consent to continue participation in the study, possible death of the patient during the study

Intervention groups
Granisetron and Droperidol Group: Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram and 1.25 mg of Droperidol (Panpharma Pharmaceutical Company – France), both administered intravenously. Granisetron and Dexamethasone Group:Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram and 8 mg of Dexamethasone (Caspian Tamin Rasht Pharmaceutical Company – Iran). Granisetron and Saline Group: Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram along with normal saline.

Main outcome variables
Nausea, vomiting, sedation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N202**
Registration date: **2026-04-25, 1405/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-25, 1405/02/05**
Update count: **0**

Registration date
2026-04-25, 1405/02/05

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-19, 1405/01/30

Expected recruitment end date

2027-04-19, 1406/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of droperidol and granisetron with dexamethasone and granisetron in the control of postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Public title

Comparison of droperidol and granisetron with dexamethasone and granisetron in the control of postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for laparoscopic cholecystectomy ASA class I or II both of gender Having informed consent to participate in the study Patients with no history of renal, hepatic, or cardiovascular disease Absence of any history of drug abuse, alcohol use, or chronic analgesic consumption Absence of a history of malignancy No history of hypertension, diabetes, or hematologic/vascular disorders No history of psychiatric or psychotic disorders No history of Parkinson’s disease, movement disorders, or chemotherapy No known sensitivity to study medications and no seasonal allergies All patients undergoing general anesthesia Surgery performed by a surgeon Surgical duration ranging from 60 to 150 minutes

Exclusion criteria:

Lack of consent to continue participation in the study Possible death of the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Random chain concealment is done by opaque envelope method

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be established as a double-blind trial. None of the patients will be aware of the type of medication they are receiving. These medications will be administered to the patients by the anesthesiologist. Each medication will be drawn into a separate syringe, which will be covered with a label, and its contents will not be identifiable. Furthermore, the medications in each syringe will be coded, and only the primary supervisor, who is an anesthesiologist, will know their contents. The intern responsible for recording outcomes will not be aware of the patient grouping or the coding system. Patients will be assessed based on their medical record number, and the collected data will be handed over to the attending physician

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Arak University of Medical Sciences

Street address

Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2026-04-12, 1405/01/23

Ethics committee reference number

IR.ARAKMU.REC.1405.034

Health conditions studied

1

Description of health condition studied

Cholecystectomy surgery

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description
Incidence of nausea
Timepoint
Recovery and 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Score 0 to 10

2

Description
Vomiting
Timepoint
Recovery and 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Score 0 to 4

3

Description
Sedation
Timepoint
Recovery and 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram and 1.25 mg of Droperidol (Panpharma Pharmaceutical Company – France), both administered intravenously.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram and 8 mg of Dexamethasone (Caspian Tamin Rasht Pharmaceutical Company – Iran).
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients will receive Granisetron (Caspian Tamin Rasht Pharmaceutical Company – Iran) at a dose of 20 micrograms per kilogram along with normal saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
Valiasr hospital, Valiasr squre
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University Of Medical Sciences
Full name of responsible person
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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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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, Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Sosanabadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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