Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of metoclopramide and promethazine in the prevention of nausea and vomiting after laparoscopic cholecystectomy: a double-blind clinical trial

Protocol summary

Study aim
Comparison of the efficacy of Metoclopramide and Promethazine in the prevention of post Laparoscopic Cholecystectomy nausea and vomiting

Design
This double-blind randomized study with parallel groups will be performed on 60 patients undergoing cholecystectomy. Patients will be randomly divided into two groups by tossing a coin. Intervention group 1: Receive 10 mg intravenous metoclopramide. Second intervention group: receive 1 mg / mg intravenous promethazine.

Settings and conduct
This randomized study will be performed in patients undergoing laparoscopic cholecystectomy referred to Shahid Mohammadi Hospital in Bandar Abbas. Patients will be divided into two groups if they meet the inclusion criteria by throwing coins and the degree of vomiting nausea will be measured in them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with ASA class one and two and consent to participate in the study. Exclusion criteria: Allergy to metoclopramide or promethazine, severe cardiovascular disease, patient with a history of motion sickness, history of severe nausea and vomiting after surgery

Intervention groups
Intervention group 1: They receive 10 mg of intravenous metoclopramide. Intervention group 2:They receive 1 mg / kg intravenous promethazine.

Main outcome variables
Nausea-vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190528043737N2**
Registration date: **2020-09-17, 1399/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-17, 1399/06/27**
Update count: **0**

Registration date
2020-09-17, 1399/06/27

Registrant information

Name
Mehrdad Malekshoar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3333 3280

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-29, 1399/01/10

Expected recruitment end date
2020-12-30, 1399/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of metoclopramide and promethazine in the prevention of nausea and vomiting

after laparoscopic cholecystectomy: a double-blind clinical trial

Public title
Comparison of the effect of metoclopramide and promethazine in the prevention of postoperative nausea and vomiting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA کلاس یک و دو
Exclusion criteria:
ASA above two Allergy to metoclopramide or promethazine Severe cardiovascular disease Patient with a history of motion sickness History of severe nausea and vomiting after surgery Emergency operation Severe renal and hepatic impairment
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients participating in the present study were randomly divided into two groups of metoclopramide and promethazine by tossing coins.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participant in the present study, the researcher, and the data collector were unaware of which group the individuals belonged to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Bandar Abbas Shahid Chamran Blvd.
City
Hormozgan
Province
Hormozgan
Postal code
7914964157
Approval date
2019-09-05, 1398/06/14
Ethics committee reference number
IR.HUMS.REC.1398.100

Health conditions studied

1

Description of health condition studied
Cholecystectomy
ICD-10 code
K91.86
ICD-10 code description
Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description
Nausea-vomiting
Timepoint
Moment of recovery, 30 minutes, first and second hours of recovery
Method of measurement
Vomiting nausea questionnaire

Secondary outcomes

1

Description
blood pressure
Timepoint
Moment of recovery, 30 minutes, first and second hours of recovery
Method of measurement
Monitoring device

2

Description
heart beat
Timepoint
Moment of recovery, 30 minutes, first and second hours of recovery
Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group1: They receive 10 mg of intravenous metoclopramide
Category
Treatment - Drugs

2

Description
Intervention group2: They receive 1 mg / kg intravenous promethazine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Mehrdad Malek Shoar
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Sponsors / Funding sources

1

Sponsor
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mehrdad Malek Shoar
Position
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
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