

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 76 3333 3280

Email address

mehrdad.malekshoar@hums.ac.ir

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:

کلاس یک و دو ASA

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

Street address

Bandar Abbas Shahid Chamran Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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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