

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effect of oral betahistin in reducing of nausea and vomiting after laparoscopic cholecystectomy with general anesthesia

Protocol summary

Study aim

The effect of oral betahistine reduce post operative nausea and vomiting (ponv) in cholecystectomy laparoscopic surgery with general anesthesia

Design

The study was performed as a clinical trial, with a control group, with parallel groups, two-way blind, approved (by blocking method with random allocation software), two-way blind, phase 3 on 120 patients.

Settings and conduct

The study population is patients who are candidates for elective laparoscopic cholecystectomy referred to Imam Khomeini Medical Center in Sari. After obtaining informed consent, the interventions were performed on 120 patients 3 hours before surgery (by the project nurse). The severity of nausea and vomiting, the amount of ondansetron and opioids used and other possible drug side effects including dry mouth, headache, itching and skin rash were evaluated and recorded after recovery in consciousness and then in surgery and 24 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient's desire to participate in the study; No history of betahistine allergy; No history of gastrointestinal disease and cardiovascular disease and respiratory problems. Exclusion criteria: Patients with uncontrolled diabetes; History of nausea and vomiting and taking anti-nausea and vomiting drugs in 24 hours before surgery; Middle ear disease; Pregnancy; High blood pressure.

Intervention groups

Betahistine 16 mg tablets (manufactured by Octovorco) orally, 3 hours before surgery. Control group: An oral placebo (Starch composition and similar in size and shape to betahistine tablets) 3 hours before surgery.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201225049829N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **retrospective**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Masoume Enayati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4000

Email address

masoumeenayati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2019-10-22, 1398/07/30

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-10-21, 1399/07/30

Scientific title

Effect of oral betahistin in reducing of nausea and vomiting after laparoscopic cholecystectomy with general anesthesia

Public title

Effect of oral betahistin in reducing of nausea and vomiting after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's desire to participate in the study and gain informed consent Candidate for elective laparoscopic cholecystectomy Age between 15 to 60 years No history of betahistine allergy No history of gastrointestinal disease and cardiovascular disease and respiratory problems

Exclusion criteria:

Patients with uncontrolled diabetes Underlying gastrointestinal disease History of nausea and vomiting and taking anti-nausea and vomiting drugs in 24 hours before surgery Middle ear disease Pregnancy Patients with BMI > 35 High blood pressure, cardiovascular disease, diarrhea with respiratory problems If the laparoscopic surgery becomes an open cholecystectomy

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is two-stage. In the first stage, with the available sampling method, 120 patients are assigned to the intervention and control groups using the blocking method. The random allocation process is done by block allocation method with random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind and statistical expert, project physicians and patients are unaware of the placement of patients in treatment groups and the data collection form is completed by the project nurse who is unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Valiasr Blv., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.058

Health conditions studied

1

Description of health condition studied

Postoperative nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Severe nausea

Timepoint

At times 1, 3, 6, 12, 24, 48 after surgery

Method of measurement

NRS (numerical rating scale)

2

Description

Vomiting

Timepoint

At times 1, 3, 6, 12, 24, 48 after surgery

Method of measurement

NRS (numerical rating scale)

Secondary outcomes

1

Description

The amount of ondansetron and narcotics consumed

Timepoint

At times 1, 3, 6, 12, 24 and 48 hours after surgery

Method of measurement

Questionnaire

2**Description**

Dry mouth

Timepoint

At times 1, 3, 6, 12, 24 and 48 hours after surgery

Method of measurement

Questionnaire

3**Description**

Headache

Timepoint

At times 1, 3, 6, 12, 24 and 48 hours after surgery

Method of measurement

Questionnaire

4**Description**

Itching

Timepoint

At times 1, 3, 6, 12, 24 and 48 hours after surgery

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: Betahistine 16 mg tablets (manufactured by Octovorco) orally, 3 hours before surgery.

Category

Treatment - Drugs

2**Description**

Control group: An oral placebo (made by Sari School of Pharmacy, with starch composition and similar in size and shape to betahistine tablets) 3 hours before surgery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Masoume Enayati

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Razi street, Sari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Masoume Enayati

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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

Not applicable

Data Dictionary

Not applicable