Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of betahistine on post-operative nausea and vomiting in pateints undergoing laparascopic cholecystectomy

Protocol summary

Study aim
The aim of this study was to evaluate the effect of betahistine in preventing nausea and vomiting after surgery of laparoscopic cholecystectomy.

Design
70 patients randomly entered into one of two parallel groups of study or control. Study will be double blinded.

Settings and conduct
This study will be performed in Urmia Imam Khomeini Hospital .90 minutes before surgery, the intervention group will receive 8 mg of oral betahistine and placebo will be given to the control group. The anesthetic method and the drugs used for anesthesia will be the same for both groups.Up to 2 hours after the operation, every 30 minutes, ask the patients about nausea and vomiting, and they will be recorded in the questionnaire. Patients and reviewers will not be aware of the type of medication and placebo.

Participants/Inclusion and exclusion criteria
patients aged 20-60 years undergoing laparoscopic cholecystectomy.Exclusion criteria include: asthma, pheochromocytoma, gastroesophageal reflux, severe obesity, BMI 35, pregnancy, breast feeding, kidney failure, history of drug addiction and alcoholism, diabetes and gastrointestinal obstruction.

Intervention groups
90 minutes before surgery, the intervention group will receive 8 mg of oral beta-thiostin and placebo will be given to the control group.

Main outcome variables
Post-operative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170408033280N2**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **prospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date
2019-01-02, 1397/10/12

Registrant information

Name
Ebrahim Hassani

Name of organization / entity
Urmia University of Medical Sciences

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Iran (Islamic Republic of)

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+98 44 3346 8967

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-05-21, 1398/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of betahistine on post-operative nausea and vomiting in pateints undergoing laparascopic cholecystectomy

Public title
The effect of betahistine on post-operative nausea and

vomiting in patients undergoing laparascopic cholecystectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
patients undergoing laparascopic cholecystectomy from 20 to 60 years

Exclusion criteria:
Asthma Pheochromocytoma Gastroesophageal reflux severe obesity difficult airway pregnancy lactation liver and kidney diseases history of drug addiction and alcoholism neuromuscular diseases Psychiatric disorders diabetes mellitus gastrointestinal obstruction Alcoholism

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to one of the two groups on the basis of last digit of the file number.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medication and placebo will be administered in the same volume to patients in both groups by a collaborator, and the patient, investigator and evaluator will not be aware of it.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences

City
Urmia- Resalat Boulevard-,

Province
West Azarbaijan

Postal code
5714783744

Approval date
2018-10-03, 1397/07/11

Ethics committee reference number
IR.UMSU.REC.1397.247

Health conditions studied

1

Description of health condition studied
Post -Operative Nausea and Vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postoperative nausea and vomiting

Timepoint
Every 30 minutes\vsakhli

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Administration of 8 mg oral Beta-histein 90 minutes before surgery

Category
Prevention

2

Description
Control group: Oral administration of the placebo 90 minutes before surgery

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Ebrahim Hassani

Street address

Ershad Avenu Imam Khmeini Hospital Anesthesiology Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Professor Iraj Mohebbi

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research@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Ebrahim Hassani

Position
Head of Department

Latest degree
Specialist

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

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available