

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The effect of Betahistine on nausea and vomiting after Laparoscopic Cholecystectomy

Protocol summary

Study aim

The effect of betahistine on nausea and vomiting after Laparoscopic Cholecystectomy

Design

Clinical trial with control group, randomized with SPSS software, single blind, phase 3 on 80 patients.

Settings and conduct

In the study of a single blind clinical trial in Azerbaijan Azerbaijan Hospital in Urmia, patients will be randomly divided into two groups of 40 using computer crash software, all participants are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients between the ages of 20 and 70 undergoing Laparoscopic Cholecystectomy. Exclusion criteria: people with BMI above 35, drug allergy, receiving anti-inflammatory drug 24 hours before surgery.

Intervention groups

In one group of patients, Betahistine will be given and in another group, a Placebo will be given 3 hours before the operation.

Main outcome variables

Severity of nausea and vomiting, Frequency of vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200902048594N1**

Registration date: **2020-09-22, 1399/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-22, 1399/07/01**

Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name

Aida Madani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3224 9432

Email address

pinarmadani94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Betahistine on nausea and vomiting after Laparoscopic Cholecystectomy

Public title

The effect of Betahistine on nausea and vomiting after surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing Laparoscopic Cholecystectomy

Exclusion criteria:

BMI more than 35 Allergy to drugs Receive anti-inflammatory medication 24 hours before surgery

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups A and B using SPSS software and simple randomization. Group A patients receive placebo and group B patients receive betahistine.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are fully aware of the intervention and have sufficient satisfaction, but are unaware of grouping (A, B). After collecting all the data, the information will be analyzed. As stated in the intervention groups, the placebo was an empty drug that looked similar to betahistine

Placebo

Used

Assignment

Other

Other design features

Individuals are randomly divided into two groups, the first group receiving Betahistine and the second group receiving Placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Islamic Azad University - Shahrood Branch

Street address

Central building, Islamic Azad University, next to the gas station, Daneshgah Blvd, Shahrood, Semnan

City

Shahrood

Province

Semnan

Postal code

3614871151

Approval date

2019-07-04, 1398/04/13

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1398.008

Health conditions studied

1

Description of health condition studied

postoperative nausea and vomiting

ICD-10 code

R11.2

ICD-10 code description

Nausea with vomiting, unspecified

Primary outcomes

1

Description

Score of nausea and vomiting after Laparoscopic Cholecystectomy

Timepoint

Patients will receive medication 3 hours before cholecystectomy.

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Patient satisfaction with nausea and vomiting control

Timepoint

The first 30 minutes and 30 minutes to 24 hours after the operation will be asked.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Betahistine at a dose of 16 mg from Ecterco factory, which is given to patients 3 hours before laparoscopic cholecystectomy.

Category

Rehabilitation

2

Description

Control group: placebo which is prepared as an empty medicine with a betahistine-like appearance prepared in Urmia School of Pharmacy which will be given 3 hours before the operation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Azarbaijan hospital

Full name of responsible person

Dr. Jalal Pourghasem

Street address

Daneshkade ave

City

Urmia

Province

West Azarbaijan

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5715933766

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pinarmadani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Fatemeh amirkhalili

Street address

Khatam ol Anbia hospital, shahrood town

City

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Province

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3619943189

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University Shahrood Branch

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Dr.Fateme Amirkhalili

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

22 Bahman St. - 12th Alley - Fateh Doctors Building -
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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