

# 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

**Postal code**

5715933766

**Phone**

+98 44 3224 9432

**Email**

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**

Shahrood

**Province**

Semnan

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3619943189

**Phone**

+98 23 3239 0360

**Email**

pinarmadani@gmail.com

**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 -  
First Floor - Unit 3

**City**

Shahrood

**Province**

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**Postal code**

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**Phone**

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**Email**

dr.amirkhalili@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr.Fateme Amirkhalili

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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