# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Sep 2026

## Comparison of Metoclopramide and Ginger capsule in prevention of Laparoscopic Cholecystectomy postoperative vomiting in Khatam al-Anbiya hospital in Shahroud, Iran in 2019

## Protocol summary

**Study aim**
Comparison of metoclopramide and ginger capsules in the prevention of postoperative vomiting of laparoscopic cholecystectomy

**Design**
Clinical trials with control group, with parallel groups, Double blinded, randomized. Sample size 100, phase 2-3

**Settings and conduct**
This study will be performed on persons undergoing laparoscopic cholecystectomy in Shahrod Khatam Al-Anbiya hospital in 2019. Patients will be randomly assigned into intervention and control groups and the intervention group will receive one gram ginger half an hour before the surgery and the control group 10 mg metoclopramide half an hour before surgery. Patients, outcome investigator and the analyzers will not have any information about prescribed drugs.

**Participants/Inclusion and exclusion criteria**
Major entry conditions include informed consent for entering the study, indication of laparoscopic cholecystectomy surgery under general anesthesia, ability to swallow capsules. Major not entry conditions include having any disorders with signs of nausea and vomiting like motion sickness, history of taking anti-nausea and vomiting drugs within three days before surgery, history of hypersensitivity to ginger or metoclopramide, bowel obstruction, hepatitis.

**Intervention groups**
The intervention group will receive one gram of ginger half an hour before the laparoscopic cholecystectomy. The control group will receive 10 mg oral metoclopramide half an hour before the laparoscopic cholecystectomy.

**Main outcome variables**
Nausea and vomiting

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190601043782N1**
Registration date: **2019-07-16, 1398/04/25**
Registration timing: **prospective**

Last update: **2019-07-16, 1398/04/25**
Update count: **0**

**Registration date**
2019-07-16, 1398/04/25

**Registrant information**

**Name**
Yasaman Moridi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3763 4487

**Email address**
hasmic71@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-07-23, 1398/05/01

**Expected recruitment end date**
2020-03-19, 1398/12/29

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of Metoclopramide and Ginger capsule in prevention of Laparoscopic Cholecystectomy postoperative vomiting in Khatam al-Anbiya hospital in Shahroud, Iran in 2019

**Public title**
The effect of Metoclopramide and Ginger capsule in prevention of Laparoscopic Cholecystectomy postoperative vomiting

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Informed consent to enter the study Indication of laparoscopic cholecystectomy under general anesthesia Ability to swallow capsules

**Exclusion criteria:**
Having any type of cancer Pregnancy Having any disorders with signs of nausea and vomiting like motion sickness ... History of taking anti-nausea and vomiting drugs within three days before surgery History of hypersensitivity to ginger or metoclopramide Bowel obstruction Hepatitis Long-term treatment with corticosteroids Diabetes Obesity (BMI greater than 30) History of digestive problems such as reflux Smoking, alcohol drinking, drug abuse Taking anticoagulants such as aspirin, warfarin, etc. Taking medications that interact with metoclopramide, such as haloperidols, phenothiazines, etc.

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The computerized block randomization (block sizes of 4 and 6) will carried out in this study. An independent clinical epidemiologist, who will not involved in the conduct of the study using a computerized block randomization program (STATA14 software) will produce the allocation codes. The randomization sequences will be concealed in opaque, sealed envelopes. The research assistant will open sealed, numbered, opaque envelopes containing allocation codes. The eligible participants will be randomized to two equal groups (ginger or metoclopramide) according to the randomization list after signing informed consent form.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Patients will not be aware of the type of medication they receive and the second executor of the research project will complete the questionnaire at the end of the treatment without awareness about two groups. Also the data will be analyzed without any information about group allocation.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee on Biomedical Research of the Islamic Azad University of Shahroud Branch

**Street address**
Islamic Azad University of Shahrood Branch, Blvd university,Shahroud Town

**City**
Shahroud

**Province**
Semnan

**Postal code**
3619943189

**Approval date**
2019-01-13, 1397/10/23

**Ethics committee reference number**
IR.IAU.SHAHROOD.REC.1397.020

## Health conditions studied

### 1

**Description of health condition studied**
Patients underwent laparoscopic cholecystectomy

**ICD-10 code**
K80-K87

**ICD-10 code description**
Disorders of gallbladder, biliary tract and pancreas

## Primary outcomes

### 1

**Description**
Nausea

**Timepoint**
Measure the severity of nausea 30 minutes, 1 hour, 6 hours and 12 hours after surgery

**Method of measurement**
Visual analogue scale

**2**

**Description**
Vomiting
**Timepoint**
Measure the frequency of vomiting 30 minutes, 1 hour, 6 hours and 12 hours after surgery
**Method of measurement**
According to the patient record

## Secondary outcomes

**1**

**Description**
Blood pressure
**Timepoint**
30 minutes, 1 hour, 6 hours and 12 hours after surgery
**Method of measurement**
Mercury pressure gauge

**2**

**Description**
Pain
**Timepoint**
30 minutes, 1 hour, 6 hours and 12 hours after surgery
**Method of measurement**
Visual analogue scale

## Intervention groups

**1**

**Description**
Intervention group: 1 g ginger (4 capsules of 250 mg of zintoma from Isfahan Pharmaceutical Company)
**Category**
Treatment - Drugs

**2**

**Description**
Control group: 10 mg oral metoclopramide (4 capsules each containing one quarter tablet of metoclopramide 10 mg produced by Hakim Pharmaceutical Company in Tehran)
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khatam Al-Anbiya Hospital in Shahrood
**Full name of responsible person**
Yousef Kolookhi
**Street address**
University Blvd - Shahrud Islamic Azad University
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dryousefkolookhianestezi@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**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**
Islamic Azad University
**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**
Islamic Azad University
**Full name of responsible person**
Yousef kolookhi
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**

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## Person responsible for updating data

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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**
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