Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 51 3763 4487

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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