

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effectiveness and safety of ginger in preventing nausea and vomiting after cholecystectomy: a double-blind clinical trial

Protocol summary

Study aim

Evaluating the effectiveness and safety of ginger in preventing nausea and vomiting after cholecystectomy

Design

Double-blind, randomized, placebo-controlled clinical

Settings and conduct

This study will be conducted in the surgery department of Rahmon Hospital, Yazd. The patients will be divided into two groups receiving Xintoma capsule and placebo by random permutation block method. Each patient will be identified with a number and the list of numbers of people who should be placed in each group will be given to the nurses and the participants, researchers, doctors and the data collectors will be unaware of this list.

Participants/Inclusion and exclusion criteria

Input criteria include: Age 16 years and older - Admitted to Rahmon hospital in Yazd due to cholecystectomy - Not receiving antiemetic drugs - Not taking Zintoma drug in the past one month - No history of allergic reaction to oral ginger - Tolerating the oral drugs - Being admitted to the internal surgery department General for 2 days - informed consent of the patient or his legal guardian
Exclusion criteria: Pregnancy or breastfeeding Receiving chemotherapy drugs

Intervention groups

Intervention group: Receiving zintoma tablet 250 mg Goldaru factory ,Take two capsules orally one hour before cholecystectomy surgery to reduce nausea and vomiting after surgery Control group: Receiving placebo witch was prepared in the pharmaceutical laboratory of Yazd Faculty of Pharmacy in the same size and color as Zintoma tablets , take two orally one hour before the cholecystectomy surgery to prevent nausea and vomiting after the operation.

Main outcome variables

Severity of nausea and vomiting and risk of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190911044744N2**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Ehsan Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 1820 5885

Email address

ehsan.mirzaei.1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness and safety of ginger in preventing nausea and vomiting after cholecystectomy: a double-blind clinical trial

Public title

Investigating the effectiveness and safety of ginger in preventing nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 16 years and older - Admitted to Rahmon hospital in Yazd due to cholecystectomy - Not receiving antiemetic drugs - Not taking Zintoma drug in the past one month - No history of allergic reaction to oral ginger - Tolerating the use of oral drugs - Being admitted to the internal surgery department General for 2 days - informed consent of the patient or his legal guardian

Exclusion criteria:

Pregnancy or breastfeeding Receiving chemotherapy drugs

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are divided into 25-person groups.using the statistical software,25 out of 50 patients are randomly assigned to treatment group and 25 to placebo group.

Unit of randomization: Individual. Tools used in randomization:computer software

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants, the principle investigator, the physicians and the data collectors are blinded. The patients who are going to receive the drug or placebo , are determined by numbers and these numbers are given to the head nurse and nurses of surgery department.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd University of Medical Sciences

Street address

Faculty of Pharmacy,Yazd, Shohada gomnam St., Alam Square

City

Yazd

Province

Yazd

Postal code

8915173149

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1402.133

Health conditions studied

1

Description of health condition studied

Prevention of nausea and vomiting after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Prevention of severe nausea and vomiting

Timepoint

Two, four, six and twelve hours after surgery

Method of measurement

questionnaire

Secondary outcomes

1

Description

Bleeding risk

Timepoint

2-4-6-12 hours after the operation

Method of measurement

blood test

Intervention groups

1

Description

Intervention group: Receiving zintoma tablet 250 mg Goldaru factory ,Take two capsules orally one hour before cholecystectomy surgery to reduce nausea and

vomiting after surgery

Category

Treatment - Drugs

2**Description**

Control group: Receiving placebo which was prepared in the pharmaceutical laboratory of Yazd Faculty of Pharmacy in the same size and color as Zintoma tablets, take two orally one hour before the cholecystectomy surgery to prevent nausea and vomiting after the operation.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

rahnemoun hospital

Full name of responsible person

Ehsan mirzaei

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Parisa seifnezhad

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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

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Proportion provided by this source

1

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Ehsan mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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