Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ctiteria 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 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.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

rahnemoun hospital

Full name of responsible person

Ehsan mirzaei

Street address

Farrokhi St., Shahid Dr. Rahmonun Hospital, Yazd

City

Yazd

Province

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Postal code

.

Phone

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Email

ehsan.mirzaei.1369@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Parisa seifnezhad

Street address

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

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Email

Parisaseif95@yahoo.com

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

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Position

Assistant Professor

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
Yazd University of Medical Sciences

Full name of responsible person
Parisa seifnezhad

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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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