

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Ginger (*Zingiber officinal*) on the prevention of postoperative nausea and vomiting after breast surgeries

#### Protocol summary

##### Study aim

Evaluation the effect of Ginger (*Zingiber officinal*) on the prevention of postoperative nausea and vomiting after breast surgeries

##### Design

80 patients will be selected as a research sample ,statistical calculations,that are eligible for inclusion in the study after the surgery completion and patient exit from anesthesia,then they will be divided in to intervention and control groups with binary blocking. in the intervention group ,4 ginger tablets (containing ginger powder)and in control group pills,similar to ginger capsules in terms of color ,odor,taste and shape ,containing ineffective pea powder will be used.the study is a randomized with parallel groups and double-blinded with control group.

##### Settings and conduct

The study will be conducted in surgery room of Imam Reza hospital .in intervention group 4 ginger tablets and in control group 4 placebo exactly similar to ginger tablets,will be prescribed one hour before surgery. immediately after completion of surgery and in recovery ,at 1,2,4,6,12,24 hours after operation ,patients will be asked about their nausea and vomiting .in this study patients and anesthesiologist will be blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion:All of Patients who Being a Candidate for Elective Surgery and Based on ASA Classification are 1 or 2 ASA Class. Exclusion:Patients with Cardiovascular, Hepatic and Kidney Disease; Patients under Prescription of anti-nausea Drugs in the last 24 hours; Pregnancy and lactation.

##### Intervention groups

Patients in the intervention group will be given four ginger capsules containing ginger powder and patients in the control group will be received two capsules weighting 250 mg,containing chickpea powder that would be similar in shape,color,taste and odor to the capsules in group one,both along with 30ml water one hour before

surgery.

##### Main outcome variables

Severity of postoperative nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150125020795N10**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

##### Registration date

2019-12-22, 1398/10/01

##### Registrant information

##### Name

Samad Golzari

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3556 6183

##### Email address

golzaris@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### 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**

Effect of Ginger (Zingiber officinal) on the prevention of postoperative nausea and vomiting after breast surgeries

**Public title**

Effect of Ginger (Zingiber officinal) on the prevention of postoperative nausea and vomiting after breast surgeries

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All of Patients who Being a Candidate for Elective Surgery and Based on ASA Classification are 1 or 2 ASA Class

**Exclusion criteria:**

Patients with Cardiovascular, Hepatic and Kidney Disease. Patients under Prescription of anti-nausea Drugs in the last 24 hours. Pregnancy and lactation

**Age**

No age limit

**Gender**

Both

**Phase**

0

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All of Patients do not Know about used Drugs in this Study and Anesthesiologist who evaluated clinical response to administered drugs

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Faculty of Medicine, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2019-07-15, 1398/04/24

**Ethics committee reference number**

IR.TBZMED.REC.1398.433

**Health conditions studied****1****Description of health condition studied**

Prevention of nausea and vomiting after surgery

**ICD-10 code**

Y84

**ICD-10 code description**

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

Severity of postoperative nausea and vomiting

**Timepoint**

Recovery and at 1,2,4,6,12 and 24 h postoperatively

**Method of measurement**

scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:Patients in the first group will be given four ginger capsules containing ginger powder with 30 ml water before surgery .

**Category**

Treatment - Drugs

## 2

### Description

Control group:patients in the second group will be received two capsules weighting 250 mg,containing pea powder that would be similar in shape,color,taste and odor to the capsules in the intervention group along with 30 ml of water one hour before surgery.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza hospital

##### Full name of responsible person

Samad Eslaam Jamal Golzari

##### Street address

Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

##### City

Tabriz

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##### Postal code

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##### Email

golzaris@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Abolghasem Joyban

##### Street address

Vice chancellor for research, Daneshgah street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

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5165665931

##### Phone

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##### Fax

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##### Email

research-vice@tbzmed.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor

##### organization/entity?

Yes

##### Title of funding source

Tabriz University of Medical Sciences

##### 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Samad Eslam Jamal Golzari

##### Position

Consultant

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Samad Eslam Jamal Golzari

**Position**

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**Latest degree**

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**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared .

**When the data will become available and for how long**

Starting 6 months after publication .

**To whom data/document is available**

Documents will be available for people working in academic institutions and also people working in businesses.

**Under which criteria data/document could be used**

There will be no specific limitations to the utilization of the data .

**From where data/document is obtainable**Dr .Samad Eslam Jamal Golzari, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 413 3341994 Fax+98 41 33341994  
golzaris@tbzmed.ac.ir**What processes are involved for a request to access data/document**

Correspondence through email only.

**Comments**