

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

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

Protocol summary

Study aim

Evaluation the effect of Ginger (*Zingiber officinal*) on the prevention of postoperative nausea and vomiting after middle ear 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: **IRCT20150125020795N11**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-25, 1398/12/06**

Update count: **0**

Registration date

2020-02-25, 1398/12/06

Registrant information

Name

Samad Golzari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+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 middle ear surgeries

Public title

Effect of Ginger (Zingiber officinal) on the prevention of postoperative nausea and vomiting after middle ear 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

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

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 1 to 9. 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

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Faculty of Medicine, Golgasht Street

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Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.TBZMED.REC.1398.432

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 post operatively

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 centers1**Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Samad Eslaam Jamal Golzari

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Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joyban

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Vice chancellor for research, Daneshgah street, Tabriz

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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

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**

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Full name of responsible person

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Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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What processes are involved for a request to access data/document

Correspondence through email only.

Comments**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

Specialist

Other areas of specialty/work

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