Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of chamomile on the incidence and severity of nausea and vomiting on patients undergoing middle ear surgery

Protocol summary

Study aim
Determine the effect of Chamomile on the incidence and severity of nausea and vomiting after middle ear surgery

Design
A controlled, parallel-group, triple-blind, randomized clinical trial on 110 patients. A coin toss was used for randomization

Settings and conduct
This three-blind study will be conducted in the otolaryngology department of Hazrat Rasool Akram Hospital in Tehran. The person taking the sample, the patient, and the statistical analyst will not know about the random allocation of the samples. 110 patients who meet the conditions to enter the study will be selected as available after providing explanations and with informed consent and will be distributed into two control and intervention groups based on random allocation by tossing a coin. In the intervention group, 50 patients Chamomile capsule of 500 mg, and in the control group, 50 patients will receive the placebo capsule one hour before the operation. After surgery, immediately after recovery from anesthesia, one hour, two hours, four hours, and six hours after recovery, patients will complete Roder's questionnaire according to their symptoms.

Participants/Inclusion and exclusion criteria
Age 18 to 65 years; ASA I and ASA II; Not taking anti-emetic medication 24 hours before surgery; platelet count above 10,000; Weight less than 90 kg; Not suffering from any liver (hepatitis, coagulation disorders), kidney (kidney stones, kidney failure) and digestive (gastric ulcer and duodenal ulcer); no history of motion sickness; not having cancer; being an NPO; No history of hypertension; no history of epilepsy; lack of pregnancy; not smoking; Absence of allergy to chamomile

Intervention groups
Intervention group: patients who receive 500 mg chamomile capsules 1 hour before surgery Control group: patients who receive placebo capsules 1 hour before surgery

Main outcome variables
Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210109049973N1**
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
parisa Moradimajd

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8670 4772

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-21, 1402/08/30

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chamomile on the incidence and severity of nausea and vomiting on patients undergoing middle ear surgery

Public title

The effect of chamomile on the incidence and severity of nausea and vomiting after middle ear surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18_65 years old ASA I and ASA II Not taking antiemetic drugs 24 hours before surgery Platlate count above 100000 Weight less than 90 kg No liver disease (hepatitis, coagulation disorder), renal disease (kidney stone, renal failure), and gastrointestinal (stomach ulcer, duodenal ulcer) No history of motion sickness No cancer Being NPo No history of hypertension No history of epilepsy No pregnancy No smoking No allergies to chamomile

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are selected as available and will be distributed in two intervention and control groups based on random allocation by tossing a coin (on the back and on the coin). In this way, the face of the coin will be related to the intervention group and the back of the coin will be related to the control group. After entering the patients and checking the entry criteria, a coin will be tossed by an unknown person to assign the groups. If the coin comes up, the patient will enter the intervention group, and if the coin comes up, the patient will be in the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blindness, according to the triple-blind approach, the capsules made with the same shape by the pharmacist are placed in two envelopes. the person doing sampling, the patient receiving medication, and finally the statistical consultant analyzing data do not know about the allocation of samples in control and intervention groups. the intervention group will be identified by the letter A and the control group by the letter B to prevent bias in collecting and recording the results of the study and to generalize the results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.IUMS.REC.1400.378

Health conditions studied

1

Description of health condition studied

Post anesthesia nausea and vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Rate of nausea and vomiting after middle ear surgery

Timepoint

Immediately after recovery from anesthesia, 1, 2, 4 and 6 hours after recovey from anesthesia

Method of measurement

Rhodes index

2

Description

Vital sign

Timepoint

Immediately, 1,2,4,6 hours after recovery from anesthesia

Method of measurement

Observation, termometer and blood pressure monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who receive 500 mg chamomile capsules 1 hour before surgery

Category

Prevention

2

Description

Control group: patients who receive placebo (corn starch) 1 hour before surgery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate rasool akram hospital

Full name of responsible person

Parisa moradi majd

Street address

Hazrate rasool akram hospital_next to Mansoori street_Niyayesh street_Saatarkhan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

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Iran university of medical sciences,next to milad tower, hemmat highway, tehran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Parisa Moradi Majd

Position

Assistant professor

Latest degree

Ph.D.

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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data cannot be shared
When the data will become available and for how long
None
To whom data/document is available
None
Under which criteria data/document could be used
Only in situations where a meta-analysis is to be performed
From where data/document is obtainable
Parisa Moradi Majd moradimajd.p@gmail.com
What processes are involved for a request to access data/document
From Email
Comments