

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Clonazepam and Ondansetron on post operation nausea and vomiting in middle ear surgeries

Protocol summary

Summary

This is a double blind clinical trial study with 192 patients aged 16-55 years who are scheduled for middle ear surgeries. The study groups, each consist of 64 patients: group A will receive 2 mg of Clonazepam, po, 2 hours before the operation and group B and group C will receive placebo at this time; on induction time, group B will receive 2cc (4mg) of Ondansetron (IV) and group B and C will receive placebo (2cc normal saline). Post operation nausea and vomiting will be checked. Mental disorders, psychiatric problem, menstruation cycle, some of drugs consumption, migraine headache, smoking, and motion sickness will be excluded. All of the patients will receive the same method of anesthesia.

General information

Acronym

PONV

IRCT registration information

IRCT registration number: **IRCT138810092942N1**

Registration date: **2009-12-22, 1388/10/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-22, 1388/10/01

Registrant information

Name

Reza Sahraei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz Univrsity of Medical Sciences

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Clonazepam and Ondansetron on post operation nausea and vomiting in middle ear surgeries

Public title

Effect of Clonazepam in post operation nausea and vomiting after middle ear surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: middle ear surgeries, age 16-55 years.
Exclusion criteria: history of ponv, smoking, migraine headache, some of medications, menstruation cycle, psychiatric problem, motion sickness.

Age

From **16 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 192

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Ave.

City

Shiraz

Postal code

7416899999

Approval date

empty

Ethics committee reference number

4964

Health conditions studied

1

Description of health condition studied

post operation nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

nausea and vomiting

Timepoint

Every 30 minutes

Method of measurement

asking from patient, nausea and vomiting score 0, 1-3 and 3<

Secondary outcomes

1

Description

vertigo

Timepoint

every 30 minutes

Method of measurement

asking from patient

Intervention groups

1

Description

Group C: placebo, po, 2 hours before the operation

Category

Placebo

2

Description

Group A: 2mg of Clonazepam, po, 2 hours before the operation

Category

Treatment - Drugs

3

Description

Group A: 2 cc of normal saline, IV, after induction

Category

Placebo

4

Description

Group B: placebo, po, 2 hours before the operation

Category

Placebo

5

Description

Group B: 2 cc (4 mg) of Ondansetron, IV, after induction

Category

Treatment - Drugs

6

Description

Group C: 2 cc of normal saline, IV, after induction

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili and Dastgheib hospital
Full name of responsible person
Dr. Reza Sahraei
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor For Research, Shiraz University Of
Medical Sciences
Full name of responsible person
Eskandari
Street address
Zand Ave.
City
Shiraz
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice Chancellor For Research, Shiraz University Of
Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty