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
Jahrom University of Medical Scienses
Country
Iran (Islamic Republic of)
Phone
+98 79 1444 7750
Email address
sahraeir@sums.ac.ir

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 vometing
Timepoint
Every 30 minutes
Method of measurement
asking from patiant, nausea and vometing score 0, 1-3 and 3<

Secondary outcomes

1

Description
vertigo
Timepoint
every 30 minutes
Method of measurement
asking from patiant

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
Street address
City
Shiraz

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
Full name of responsible person
Dr. Sina Ghafari
Position
Assistant professor
Other areas of specialty/work
Street address
Faghihi Hospital, Zand Ave
City
Shiraz
Postal code
7416899999
Phone
+98 71 1233 7636
Fax
+98 71 1231 8072
Email
sighafari@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Hadavi
Position
Assistant professor
Other areas of specialty/work
Street address
Faghihi Hospital, , Zand ave.
City
Shiraz
Postal code
7416899999
Phone
+98 71 1233 7636
Fax
+98 71 1231 8072
Email
hadavimr@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz Univerity of Medical Sciences
Full name of responsible person
Dr. Sina Ghafari
Position
Assistatprofessor
Other areas of specialty/work
Street address
Faghihi Hospital , Zand Ave.
City
Shiraz
Postal code
7416899999
Phone
+98 71 1233 7636
Fax
+98 71 1231 8072
Email
sighafari@sums.ac.ir
Web page address

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