Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of the effect of intravenous diphenhydramine and ondansetron on post middle ear surgery nausea and vomiting

Protocol summary

Study aim
Prevention of nausea and vomiting in middle ear surgery

Design
Clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, sample of 100 patients. Randlist software was used for randomization.

Settings and conduct
The study will be performed in the recovery department of Imam Reza Hospital in Tabriz. the variables of nausea, vomiting will be completely examined and recorded by the anesthesiologist in both groups.The severity of postoperative nausea and vomiting in recovery at 4, 8, 12, 16,20 and 24 hours and based on scoring (0 = no nausea and vomiting, 1 = nausea, 2 = vomiting and 3 = vomiting more than 2 times) Will be reviewed .In this study, patients and anesthesiologists are blinded to the study,but the theses owner student is fully aware of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:All people aged 18 to 60 are candidates for middle ear surgery Has ASA grade,class I&II Exclusion criteria:History of nausea and vomiting after surgery History of migraine headache History of digestive problems Pregnant and in menstruating period History of motion sickness Take anti-nausea medication 48 hours before surgery

Intervention groups
Intervention group:In this group, they will receive 4 mg of intravenous ondansetron before induction of anesthesia. Control group:In this group, 50 mg of diphenhydramine will be injected intravenously before induction of anesthesia.

Main outcome variables
Severity of nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150217021121N5**
Registration date: **2020-08-05, 1399/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-05, 1399/05/15**
Update count: **0**

Registration date
2020-08-05, 1399/05/15

Registrant information

Name
Reza Movassaghi Gargari

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparison of the effect of intravenous diphenhydramine and ondansetron on post middle ear surgery nausea and vomiting

Public title
the effect of intravenous diphenhydramine and ondansetron on nausea and vomiting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All people aged 18 to 60 are candidates for middle ear surgery Has ASA grade,class I&II
Exclusion criteria:
History of nausea and vomiting after surgery History of migraine headache History of digestive problems Pregnant and in menstruating period History of motion sickness Take anti-nausea medication 48 hours before surgery
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
We will construct 6 blocks in AABB, BBAA, ABAB, BABA, ABBA and BAAB using four blocks. We will assign 1 to 6 for each block. Then, using the random number table, based on the sample size, 25 units of 4 blocks will be selected so that we consider having 50 people in control group (A) and 50 people in intervention group (B). Therefore, we will do block randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, the thesis owner student provides the drugs to the anesthesiologist and is the only person who is not blind to the study.The anesthesiologist, who is in charge of the patient's anesthesia management, injects the drug through coded syringes that have already been prepared by the thesis owner.So that anesthesiologist is unaware of the injected drug to patient during injection.The anesthesia nurse, who is responsible for collecting information and variables from the patient and is unaware of the type of prescribed drug, fills in the checklist during surgery and recovery.The patient is also unaware of the type of Injecting drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences
Street address
Vice chancellor for research, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5183915881
Approval date
2020-07-13, 1399/04/23
Ethics committee reference number
IR.TBZMED.REC.1399.389

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting
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
In the post-anesthesia care department every 24 hours for 24 hours after surgery
Method of measurement
Based on scoring (0 = no nausea and vomiting, 1 = nausea, 2 = vomiting and 3 = vomiting more than 2 times

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In this group, they will receive 4mg of

intravenous ondansetron before induction of anesthesia.

Category

Treatment - Drugs

2

Description

Control group:In this group, 50 mg of diphenhydramine will be injected intravenously before induction of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Reza Movvassaghi

Street address

Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences research vice chancellor

Full name of responsible person

Dr Abolghasem Joyban

Street address

Vice chancellor for research, Daneshgah street, Tabriz

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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 research vice chancellor

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

Reza Movvassaghi

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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 potential data can be shared after making peoples unrecognizable.

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments