

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 thesis 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)

Phone

+98 41 3336 8740

Email address

movassaghir@tbzmed.ac.ir

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 1994

Fax

+98 41 3334 1994

Email

rz_movassaghi@yahoo.com

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3335 7310

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

Street address

Departement of Anesthesiology, Faculty of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 1994

Fax

+98 41 3334 1994

Email

rz_movassaghi@yahoo.com

Person responsible for scientific 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

Street address

Departement of Anesthesiology, Faculty of Medicine,
Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 1994

Fax

+98 41 3334 1994

Email

rz_movassaghi@yahoo.com

Person responsible for updating data

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

Street address

Departement of Anesthesiology, Faculty of Medicine,
Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 1994

Fax

+98 41 3334 1994

Email

rz_movassaghi@yahoo.com

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

Dr .Reza Movassaghi, Department of Anesthesiology,
Faculty of Medicine, Golgasht Street, Tabriz East
Azarbaijan Islamic Republic of Iran Phone+98 413
3341994 Fax+98 41 33341994
rz_movassaghi@yahoo.com

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