

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of preoperative Ondansetron and Dexamethasone in prevention of postoperative nausea and vomiting after middle ear surgeries

Protocol summary

Summary

Nausea and vomiting are common complications after anesthesia and surgery. Patients undergoing middle ear surgery are exposed to a higher risk of PONV (Postoperative Nausea & Vomiting). These complications may alter the results of reconstruction and anatomical alignments. Numerous antiemetics have been studied to prevent and treat PONV in patients undergoing middle ear surgeries. The aim of this study is to compare the effect of intravenous Ondansetron and Dexamethasone on these complications. To do this, in a Double-blind randomized controlled clinical trial 219 patients who undergoing middle ear surgery randomly will be divided into 3 groups (O, D and P). The patients in group O will be received Ondansetron (4 mg IV), group D patients will be received Dexamethasone (8 mg IV), and group P patients will be received placebo prior to anesthetic induction. Using Belliville's scoring system, the incidence of PONV and its severity will be documented during the 24-hour period after surgery and compared between the three groups. The quantitative variables will be compared using one-way ANOVA and a post hoc Tukey test. The comparison of qualitative variables will be performed using contingency tables and chi-squared test as well as Fisher's exact test at $p < 0.05$. Inclusion criteria : patients undergoing ear surgical operations with physical conditions of ASA I or II exclusion criteria : Patients with digestive problems, or with a history of treatment with antiemetics and nausea in the last 24 hours and also severe obese patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106154005N4**
Registration date: **2011-07-04, 1390/04/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-04, 1390/04/13

Registrant information

Name

Khosro Kolahdouzan

Name of organization / entity

Faculty of Paramedical Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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kolahdozank@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of preoperative Ondansetron and

Dexamethasone in prevention of postoperative nausea and vomiting after middle ear surgeries

Public title
Comparison of Ondansetron and Dexamethasone in prevention of nausea and vomiting

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing ear surgical operations with physical conditions of ASA I or II;
Exclusion criteria: Patients with digestive problems, or with a history of treatment with antiemetics and nausea in the last 24 hours and also severe obese patients

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **219**

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

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

Approval date

2009-04-09, 1388/01/20

Ethics committee reference number

1296

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea

Timepoint

16-24 hours after operation 8-16 hours after operation

2-8 hours after operation 0-2 hours after operation

Method of measurement

questionnaire

2

Description

Vomiting

Timepoint

16-24 hours after operation 8-16 hours after operation

2-8 hours after operation 0-2 hours after operation

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Before induction of anesthesia, 4 mg of Ondansetron, will be administered intravenously to Ondansetron group respectively. The volume of the drug prescribed will be 3 mL. Premedication will given using Midazolam at a dose of 0.15 mg/kg and Fentanyl at a dose of 1-2µg/kg. Induction will be carried out with Propofol at a dose of 1-2.5 mg/kg and Atracurium at a dose of 0.5 mg/kg. Anesthetic maintenance will be performed using "Total Intravenous Anesthesia" method and also through Propofol at a dose of 10-20 mg/kg/min and Remifentanyl at a dose of 0.5 µg/kg/min.

Category

Treatment - Drugs

2

Description

Before induction of anesthesia, 8 mg of Dexamethasone will be administered intravenously to Dexamethasone group, respectively. The volume of the drug prescribed will be 3 mL in group. Premedication will given using Midazolam at a dose of 0.15 mg/kg and Fentanyl at a dose of 1-2µg/kg. Induction will be carried out with

Propofol at a dose of 1-2.5 mg/kg and Atracurium at a dose of 0.5 mg/kg. Anesthetic maintenance will be performed using "Total Intravenous Anesthesia" method and also through Propofol at a dose of 10-20 mg/kg/min and Remifentanyl at a dose of 0.5 µg/kg/min.

Category

Treatment - Drugs

3

Description

Before induction of anesthesia, distilled water will be administered intravenously to placebo group, respectively. The volume of the drug prescribed will be 3 mL in group. Premedication will given using Midazolam at a dose of 0.15 mg/kg and Fentanyl at a dose of 1-2µg/kg. Induction will be carried out with Propofol at a dose of 1-2.5 mg/kg and Atracurium at a dose of 0.5 mg/kg. Anesthetic maintenance will be performed using "Total Intravenous Anesthesia" method and also through Propofol at a dose of 10-20 mg/kg/min and Remifentanyl at a dose of 0.5 µg/kg/min.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mahmood Eidi

Street address

Emam Reza Hospital, Daneshgah St. Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

University of Medical Sciences, Daneshghah St, Tabriz

City

Tabriz

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,Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahmoud Eidy

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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