

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of different doses of granisetron plus dexamethasone versus ondansetron plus dexamethasone in prevention of postoperative nausea and vomiting in patients undergoing tympanoplasty

Protocol summary

Summary

Patients will randomly allocated in three groups: 1) granisetron 0.1 mg plus dexamethasone 8 mg, 2) granisetron 0.3 mg plus dexamethasone and 3) ondansetron 4 mg plus dexamethasone 8 mg. All patients will receive same premedication with midazolam and fentanyl. Induction of anesthesia will be with propofol and lidocain and muscle relaxation with atracurium. Immediately after intubation , dexamethason 8 mg will adminster to all patients. isofluran will use during anesthesia. 15 minute before tracheal extubation patients will receive 0.1 , 0.3 gransetron or 4mg ondansetron in 2ml syringes by anesthesiologist who blind about patients, group and drugs. Then the patients will follow up for post operative nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207223915N7**

Registration date: **2012-07-25, 1391/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

Email address

peirovifara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different doses of granisetron plus dexamethasone versus ondansetron plus dexamethasone in prevention of postoperative nausea and vomiting in patients undergoing tympanoplasty

Public title

comparing different drugs in prevention of post-tympanoplsty nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients that are candidate for tympanoplasty with ASA class I or II and age 15-60 year. Exclusion criteria: gastrointestinal diseases, history of treatment with anti emetics or drugs with anti emesis effects at 24 hours before surgery, BMI more than 36.5, pregnant or lactating mothers, opiate abuse, sensitivity reaction to studied drugs.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**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

Golgasht Street. Tabriz University of Medical Sciences

City

Tabriz

Postal code**Approval date**

2011-02-28, 1389/12/09

Ethics committee reference number

54/29176

Health conditions studied**1****Description of health condition studied**

post tympanoplasty nausea and vomiting

ICD-10 code

Y83.8

ICD-10 code description

Other surgical procedures

Primary outcomes**1****Description**

post operative nausea and vomiting

Timepoint

every 0-2 hours till 24 hours

Method of measurement

clinical monitoring

Secondary outcomes**1****Description**

need for anti emetic drugs

Timepoint

every 0-2 hours till 24 hours

Method of measurement

Bellville score

Intervention groups**1****Description**

dexamethasone 8 mg IV immediately after intubation for all patients plus granisetron 0.1 mg 15 minutes before extubation in group A

Category

Treatment - Drugs

2**Description**

granisetron 0.3 mg 15 minutes before extubation plus post intubation dexamethasone in group B

Category

Treatment - Drugs

3**Description**

Ondansetron 4mg 15 minutes before extubation in addition to post intubation dexamethasone in group C

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Immam Reza Hospital

Full name of responsible person

Ali peirovifar

Street address

Operation room. Immam Reza Hospital.Golgasht Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research VICE chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Golgasht Street. Tabriz University of Medical Sciences

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research VICE chancellor of 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**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Perovifar

Position

Associate professor of Anesthesiology

Other areas of specialty/work**Street address**

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Other areas of specialty/work**Street address****City**

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Postal code**Phone**

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Fax**Email****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