Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 midasolam 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
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Manizheh Mostafa Gharehbaghi
Name of organization / entity
Tabriz University of Medical Sciences
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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

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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

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Position
Associate professor of Anesthesiology

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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