

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of antiemetic effects of gabapentin and dexametason in patient who are candidates of middle are surgery

Protocol summary

Summary

After obtaining written informed consent ,elective ASA class I,II patients candidate for tympanomastoidectomy aged between 20-60 were randomly enroll ed to one of four study groups according to block randomization. Medical intervention was done 1hr before surgery as following in each group. Patients in the gabapentin group received 800mg Gabapentin (2 oral capsules) with 2cc sterile water intravenously (IV), in the second group patients received 8mg dexametason(IV) with placebo (2 oral capsules similar gabapentin) . Third group participants received 800 mg gabapentin plus 8mg dexametason(IV).The final group patients received placebo (2 oral capsules similar gabapentin) with 2 cc sterile water (IV).Patients in all groups underwent general anesthesia in the same manner, consisting of premedication with fentanyl 2µg/Kg,midazolam 2mg, followed by induction dose of sodium thiopental(5mg/kg) and atracurium 0.6 mg/kg. After intubation anesthesia were maintained by isoflurance 0/5% + propafol 50 µg / kg /m + remifentanyl (0.1µg/kg/min). Degree of nausea and vomitting is assessed until 24 hours post-operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208075225N2**

Registration date: **2012-08-20, 1391/05/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-08-20, 1391/05/30

Registrant information

Name

Seyed mohammad Mireskandari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 8931

Email address

mireskandari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Terhan University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of antiemetic effects of gabapentin and dexametason in patient who are candidates of middle are surgery

Public title

Comparison of antiemetic effects of gabapentin and dexametason in patient who are candidates of middle are surgery in the year2012 in Valiasr hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients scheduled for Tympanomastoidectomy under general anesthesia; ASA class I,II patients; patients aged between 20-60 years. Exclusive criteria : prior history of PONV; smokers;

hypersensitivity to any of study drugs; serious organ disease/dysfunction; persistent preoperative pain; prior use of analgesic; alcohol/substance abuse; a major psychiatric disorder; a bleeding disorder; peptic ulcer disease; asthma/COPD and a seizure disorder; patients who had received anti emetics within 24 hr before scheduled surgery or received sedatives (7, 8) and duration of operation more than 3 hours.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

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**

Tehran University of Medical Sciences Ethics Committee

Street address

Keshavarz Boulevard ,Tehran

City

Tehran

Postal code**Approval date**

2011-04-19, 1390/01/30

Ethics committee reference number

90/130/141

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

Vomiting

ICD-10 code

Z40-54

ICD-10 code description

Persons encountering health services for specific procedures and health care

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

Nausea and vomiting

Timepoint

Frequency of Nausea & vomiting during 24 hours post-operation

Method of measurement

According to self report of patients

Secondary outcomes

empty

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

Patients in combination group receive 2 capsule of gabapentin and 8 mg dexamethasone (2cc) intravenously

Category

Treatment - Drugs

2**Description**

Medical intervention was done 1hr before surgery as following in each group. Patients in the gabapentin group received 800mg Gabapentin (2 oral capsules) with 2cc saline normal intravenously (IV

Category

Treatment - Drugs

3**Description**

Patients in dexamethasone group received 8 mg dexamethasone(2 cc) intravenously and 2 placebo capsule identical to gabapentin.

Category

Treatment - Drugs

4**Description**

In control (placebo) group patients receive 2 cc normal saline intravenously and 2 placebo capsules orally

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Valiasr Hospital, Imam Khomeini Complex

Full name of responsible person**Street address****City**

Tehran

Position

Anesthesiologist

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

Imam Khomeini Complex

City

Tehran

Postal code**Phone**

+98 21 6119 2828

Fax**Email**

mireskandari@sina.tums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Deputy of research of Tehran university of medical sciences

Full name of responsible person

Akbar Fotoohi

Street address

Office of TUMS Public Relations, Keshavarz Blvd.

City

Tehran

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

Yes

Title of funding source

Deputy of research of Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mireskandari

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mireskandari

Position

Associate professor

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

Anesthesiology department, Imam Khomeini complex, Keshavarz boulevard

City

Tehran

Postal code**Phone**

+98 21 6119 2828

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*