

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Prophylactic effect of dexamethasone on postoperative nausea and vomiting in patients under stapedectomy

#### Protocol summary

##### Summary

Background: Nausea and vomiting after middle ear surgery is one of the most common complications after surgery; considered to become the ground for the incidence of other adverse consequences. The aim of this study was to evaluate the effect of prophylactic intravenous dexamethasone 16 mg on postoperative nausea and vomiting after stapedectomy. Methods: In a randomized double-blind controlled trial study, 70 patients candidate for stapedectomy divided into two equal groups, using the same sedation by single surgeon. While the case group received 16 mg Dexamethasone, half an hour before surgery, the control group received 4ml intravenous saline as a placebo. Patients were controlled 1-24 hours after the surgery in terms of nausea and vomiting and dependent variables such as vertigo and tinnitus.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012133181N3**

Registration date: **2012-02-28, 1390/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-02-28, 1390/12/09

##### Registrant information

##### Name

Zahra Mokhtari

##### Name of organization / entity

Otorhinolaryngology research center, Tehran  
university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6676 0269

##### Email address

zmokhtari@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2007-09-23, 1386/07/01

##### Expected recruitment end date

2009-09-23, 1388/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prophylactic effect of dexamethasone on postoperative nausea and vomiting in patients under stapedectomy

##### Public title

Effect of dexamethasone on nausea and vomiting

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: adult patients undergoing stapedectomy surgery who were referred to ENT clinic of Amiralam hospital and classification of physical status (American society of Anesthesiologist) ASA class I or II component. Exclusion criteria: motion sickness; history of GI disorder; history of diabetes and history of antiemetic drugs to 48 hours before surgery; history of taking corticosteroids, and prior history of PONV during two weeks before.

##### Age

From **15 years** old to **62 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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 Tehran University of Medical Sciences

**Street address**

Vice Chancellor for research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

**City**

Tehran

**Postal code****Approval date**

2010-12-18, 1389/09/27

**Ethics committee reference number**

85-01-48-3532

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

Stapedectomy surgery

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Nausea and vomiting

**ICD-10 code**

R11

**ICD-10 code description**

Nausea and vomiting

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

Nausea and Vomiting

**Timepoint**

1-24 hour

**Method of measurement**

observation and questionnaire

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

vertigo

**Timepoint**

1-24 hour

**Method of measurement**

questionary

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

Dexamethone, 16mg, will be injected intravenously half an hour before surgery.

**Category**

Prevention

**2****Description**

4ml normal saline, as placebo, will be injected intravenously half an hour before surgery.

**Category**

Placebo

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

Operative room of Amir Alam Hospital

**Full name of responsible person**

Zahra Mokhtari

**Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akbar Fotouhi

**Street address**

Vice Chancellor for research, Tehran University of  
Medical Sciences, Ghods St, Keshavarz Blvd

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**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, 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****Name of organization / entity**

Otorhinolaryngology Research Center, Tehran  
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**Full name of responsible person**

Zahra Mokhtari

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PhD student of Medical Physiology at Tehran  
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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*