

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

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university of medical sciences

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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

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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

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Medical Sciences, Ghods St, Keshavarz Blvd**City**

Tehran

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

Yes

Title of funding sourceVice 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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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*