

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Investigating the effect of steroid after tympanoplasty surgery on hearing level and bone conduction

Protocol summary

Summary

This study aimed to determine the positive and negative effects of corticosteroids on outcomes after Tympanoplasty surgery and applicable purpose of this study is preventing unnecessary prescribing steroids and reduction of complications .All 18-75 years patients with COM are enrolled and patients with vertigo before surgery, cholesteatoma ,previous ear surgery , active ear infections are excluded .All 20 patients ,randomly assigned to two groups; receiving and not receiving steroids (dexamethasone 8 mg in 2 doses 12 hours apart) after surgery . Other interventions such as surgery technique , taking steroid and antibiotic prophylaxis before surgery are the same in two groups and surgeons included from faculty will hold the skills in performing tympanoplasty .Then all study outcomes such as tinnitus, hearing loss (BC thresholds) and graft status in month third after surgery are considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030510041N4**
Registration date: **2014-08-13, 1393/05/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-13, 1393/05/22

Registrant information

Name

Ali Kouhi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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a-kouhi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of steroid after tympanoplasty surgery on hearing level and bone conduction

Public title

Investigating the effect of steroid after tympanoplasty surgery on hearing level and bone conduction at valiasr & Amir Alam Hospitals in 2013-2014.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Age between18-75 years;Diagnosis COM Exclusion criteria:Vertigo before surgery;Cholesteatoma;History of ear surgery; Active infection; Complete tympanic perforation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran university of Medical Sciences Building
,Keshavarz Blvd,Tehran ,Iran

City

Tehran

Postal code

Approval date

2014-02-26, 1392/12/07

Ethics committee reference number

106518-23363-48-03-92

Health conditions studied

1

Description of health condition studied

Otosclerosis

ICD-10 code

H80.9

ICD-10 code description

Otosclerosis, unspecified

Primary outcomes

1

Description

hearing assesment with bone conduction threshold

Timepoint

3 month after surgery

Method of measurement

audiometry

Secondary outcomes

1

Description

graft repair

Timepoint

after surgery

Method of measurement

examination

2

Description

tinnitus

Timepoint

after surgery

Method of measurement

examination

3

Description

vertigo

Timepoint

after surgery

Method of measurement

examination

Intervention groups

1

Description

Intervention group:two dose of 8 mg intratympanic injection Dexamethasone within 12 hours after surgery

Category

Treatment - Drugs

2

Description

Control group: not receiving intratympanic injection of 8 mg of Dexamethasone within 12 hours after surgery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Alam Hospital

Full name of responsible person

Dr.Ali Kouhi

Street address

Saadi Ave,AmirAlam hospital ,Tehran,Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Valieasr Hospital

Full name of responsible person

Dr.Amin Amali

Street address

Bagher Khan Ave,Valieasr Hospital,Tehran,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.masoud Yonesian

Street address

Keshavarz Blvd, Tehran,Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

University of Medical Sciences

Full name of responsible person

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Position

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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