

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparisons of hearing results and graft status in myringoplasty surgery in patients with chronic otitis media in the two groups receiving N2O and non receiving N2O during anesthesia in Amir Alam hospital and Valiasr hospital during the year 2013

Protocol summary

Summary

This study is designed to investigate n2o anesthesia gas effects on graft outcomes in tympanoplasty surgeries. This is an interventional clinical trial. during study patients who are candidate for tympanoplasty procedure will be enrolled in this study. patients with cholesteatoma, previous ear surgery, active infection, diabetes mellitus and tympanosclerosis will be excluded. patients are randomly allocated to two groups: anesthesia with N2O 2) anesthesia without n2o. microsurgery method will be the same in all of the patients. microscopic examination after 3 months post op will reveal graft status. also, post operative audiometry will be used to study patients hearing status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050110041N3**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Ali Kouhi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 3037

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a-kouhi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisons of hearing results and graft status in myringoplasty surgery in patients with chronic otitis media in the two groups receiving N2O and non receiving N2O during anesthesia in Amir Alam hospital and Valiasr hospital during the year 2013

Public title

Comparisons of hearing results and graft status in myringoplasty surgery in patients with chronic otitis media in the two groups receiving N2O and non receiving N2O during anesthesia in Amir Alam hospital and Valiasr hospital during the year 2013

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: candidates for tympanoplasty procedure. Exclusion criteria: cholesteatoma; previous ear

surgery; active infection; diabetes mellitus and tympanosclerosis.

Age

To 75 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 59

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

Keshavarz Blvd, Ghods st.

City

Tehran

Postal code

Approval date

2013-04-30, 1392/02/10

Ethics committee reference number

91-04-48-20459-76306

Health conditions studied

1

Description of health condition studied

Chronic otitis media

ICD-10 code

H66.9

ICD-10 code description

Otitis media, unspecified

Primary outcomes

1

Description

Tympanic membrane graft success

Timepoint

3 months post operation

Method of measurement

Microscopic examination

Secondary outcomes

1

Description

Hearing

Timepoint

3 months post operation

Method of measurement

Audiometry

Intervention groups

1

Description

Anesthesia without N2O

Category

Treatment - Drugs

2

Description

using N2O during anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehtan University of Meical Sciences-Amir Alam hospital

Full name of responsible person

Dr Ali Kouhi

Street address

Amir-Alam Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nouruz zadeh

Street address

Tehran

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
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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