

# 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

##### Email address

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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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