

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of hearing outcome between incus inposition and angular clip titanium prosthesis in patients with I-S joint erosion because chronic otitis media in 2015 to 2017 in Imam Khomeini

Protocol summary

Summary

Chronic otitis media is a prevalent disease which can cause damage to the ossicles and consequently conductive hearing reduction. An effective surgical method that can eliminate chronic infection, as well as improving the hearing ability is a great concern for otolaryngologists. The aim of this study is to compare incus inposition surgery with reconstruction with angular clip prosthesis and to determine which method can provide a better hearing outcome for patients. Patients with chronic otitis media who suffered from incus erosion and underwent Incus Inposition surgery using Incus autograft and tympanoplasty are included in this interventional study. Patients who underwent revision surgery, are in need of TROP prosthesis installment, their stapes bone is immobile and experienced graft failure are excluded from this study. This study consists of two groups, the first group includes 25 patients who underwent Incus Inposition surgery. The second group includes same number of patients who will go through reconstruction with angular clip prosthesis and tympanoplasty. Data from pre-operative and post-operative audiometry exam will be analyzed. Air bone gap and Bone conduction threshold will be calculated for each patient and the mean of Air bone gap and Bone conduction threshold will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101136554N2**

Registration date: **2017-10-28, 1396/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name

Hamed Emami

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hearing outcome between incus inposition and angular clip titanium prosthesis in patients with I-S joint erosion because chronic otitis media in 2015 to 2017 in Imam Khomeini

Public title

Comparison of two surgical methods in improvement of hearing among patients with chronic ear infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with I-S joint erosion because of chronic otitis media. Exclusion criteria : patients who underwent revision surgery ; patients who need TORP Prosthesis installment ; patients with immobile stapes bone ; patients with graft failure

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1673

Health conditions studied

1

Description of health condition studied

I-S joint erosion because of chronic otitis media

ICD-10 code

H74.2

ICD-10 code description

Discontinuity and dislocation of ear ossicles

Primary outcomes

1

Description

air bone gap

Timepoint

6 month

Method of measurement

audiometry

2

Description

Bone conduction treshold

Timepoint

6 months

Method of measurement

audiometry

Secondary outcomes

empty

Intervention groups

1

Description

reconstruction with angular clip prosthesis

Category

Treatment - Surgery

2

Description

incus inposition

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hostpital

Full name of responsible person

Dr Hamed Emami

Street address

Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Science and Technology of Tehran
University of Medical Sciences

Full name of responsible person

Dr. Masoud Yoonesian

Street address

Central department of Tehran University of Medical
Sciences, Intersection of Keshavarz blvd. and Qods St.

City

Tehran

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

Yes

Title of funding source

Department of Science and Technology of 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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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