Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison hearing results in patients with Partial Ossicular Replacement Prosthesis(PORP) titanium versus Polycel

Protocol summary

Summary

Ossicular reconstruction in patients with chronic otitis media have contributed significantly to the improvement of their hearing and because of the variety of prostheses, so we decided to compare hearing improvement after ossiculoplastic surgery between the two prostheses made of Polycel and titanium. This is a double blind randomized clinical study in a single center (Dastghaib Hospital Shiraz -Iran). Both of them audiologist who measures hearing outcome and statistician who analyzes data will be blinded. Patients divide in two groups: in the first group, 50 patients will be undergone ossicular reconstruction with titanium prosthesis and in the second group 50 patients will be undergone ossicular reconstruction with Polycel prosthesis. According to our centre routine approach, the surgery is performed in two stages: the first stage includes cleaning the middle ear from possible pathologies and tympanic membrane repair and the second stage includes ossicular reconstruction surgery. Thus, all patients requiring ossicular reconstruction surgery in the second stage surgery will be included in the study. Patients with sensorineural hearing loss and who have inadequate follow-up will be excluded. Six months after operation, primary outcome (hearing improvement) will be evaluated with pure tone audiometry tests and the two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082815496N19**
Registration date: **2016-01-21, 1394/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-21, 1394/11/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-06-21, 1392/03/31

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison hearing results in patients with Partial Ossicular Replacement Prosthesis(PORP) titanium versus Polycel

Public title

Comparison of Hearing results after ossiculoplasty: titanium versus Polycel

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion:All patients who referred due to ossicular chain reconstruction in the second stage of operation. Exclusion criteria: presence of cholesteatoma, granulation tissue in second look and tympanic membrane perforation; patients with sensorineural hearing loss; inadequate follow-up after surgery (less than 6 months)

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2015-12-08, 1394/09/17

Ethics committee reference number

IR.sums.med.rec.1394.s49

Health conditions studied

1

Description of health condition studied

Chronic otitis media with ossicular disruption

ICD-10 code

H74.3

ICD-10 code description

Other acquired abnormalities of ear ossicles

Primary outcomes

1

Description

hearing threshold

Timepoint

before operation -6 months after operation

Method of measurement

pure tone audiometry

Secondary outcomes

empty

Intervention groups

1

Description

ossicular chain reconstruction with Polycell prosthesis in control group

Category

Treatment - Surgery

2

Description

ossicular chain reconstruction with titanium prosthesis in intervention group

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Dr. Mohammad Faramarzi

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Hafez Street, Next to National Garden

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shiraz 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

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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