

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison hearing results in patients with Total Ossicular Replacement Prosthesis (TORP) titanium versus Polycel in Shiraz Shahid Dastgheib hospital

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. The study design was a randomized single-blind and patient groups are sharing. In the first group, 50 patients underwent ossicular reconstruction with titanium prosthesis and in second group 50 patient with polycel prosthesis. All patients who have conductive hearing loss due to chronic ear infections participated in the study and patients with sensorineural hearing loss and who have irregular follow-up are excluded. In all selected patients total ossicular reconstruction surgery are performed And 1 month and 6 months after the operation result (improved hearing) are evaluated with pure tone audiometry tests and compared the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205049631N1**

Registration date: **2013-08-23, 1392/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Reza Jahangiri

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison hearing results in patients with Total Ossicular Replacement Prosthesis (TORP) titanium versus Polycel in Shiraz Shahid Dastgheib hospital

Public title

Comparison of Hearing results after ossiculoplasty: titanium versus polycel

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: all patients with chronic otitis media and damage their ossicles and conductive hearing loss. Exclusion criteria: presence of cholesteatoma in second look and large tympanic membrane perforation; inappropriate follow-up after surgery and patients with

sensorineural hearing loss.

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)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand street, Shiraz

City
Shiraz

Postal code

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
ct-91-4317

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 results

Timepoint
before operation and 6 months after operation

Method of measurement
pure tone audiometry

Secondary outcomes

empty

Intervention groups

1

Description
ossicular reconstruction with polycell prosthesis in control group

Category
Treatment - Surgery

2

Description
ossicular reconstruction with titanium prosthesis in interventional group

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Dastgheib hospital

Full name of responsible person
Faramarzi Abolhasan

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellery of Research and Technology

Full name of responsible person
Hatam Gholam Reza

Street address
Zand street, Central bulding of Medical University

City
Shiraz

Grant name
طرح های پژوهشی

Grant code / Reference number

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

Title of funding source
Vice-Chancellery of Research and Technology

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

Shiraz University of Medical Sciences

Full name of responsible person

Kabood Khani Reza

Position

ENTspecialis, head and neck flowship, Research Assistant

Other areas of specialty/work

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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