

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison hearing results in patients with fluoroplastic Causse Loop Piston versus platinum/titanium (Big Easy) Piston in stapedotomy

Protocol summary

Summary

Otosclerosis is a most common cause of conductive hearing loss in adults. The aim of this study is comparing hearing improvement in patients with otosclerosis who underwent primary stapedotomy with Causse Loop Piston or Big Easy Piston prosthesis. This is a double blind randomized clinical study in a single center (Dastghaib Hospital Shiraz -Iran). Both of them audiologist who measured hearing outcome and statistician who analyzed data have been blinded. Patients divided in two groups: 89 Patients in Causse Loop Piston group and 70 Patients in Big Easy Piston. Inclusion criterion: Patients who suffered from otosclerosis and undergone stapedotomy with each of prosthesis as intervention. Exclusion criteria: Patients, who underwent stapedectomy and/or revision stapedotomy, Patients who underwent stapedotomy for reasons other than otosclerosis, patients with inadequate postoperative follow-up. Primary outcome was hearing results that were assessed 6 months after the operation and two groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011615496N3**

Registration date: **2015-08-06, 1394/05/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-06, 1394/05/15

Registrant information

Name

Sareh Roosta

Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical
Sciences

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2014-12-30, 1393/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison hearing results in patients with fluoroplastic
Causse Loop Piston versus platinum/titanium (Big Easy)
Piston in stapedotomy

Public title

Comparison of Hearing results after stapedotomy:
fluoroplastic Causse Loop Piston versus Big Easy Piston

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: 1) Patients who suffered from
otosclerosis and undergone stapedotomy with Causse
Loop Piston prosthesis (Medtronic Xomed, Jacksonville,
FL) or Big Easy Piston prosthesis (Medtronic Xomed,

Jacksonville, FL). Exclusion criteria: 1) All Patients who underwent stapedectomy; 2) Revision cases; 3) Patients who underwent stapedotomy for reasons other than otosclerosis, such as: congenital stapes fixation, malleus head fixation, trauma, chronic otitis media, and tympanosclerosis plaque; 4) Inadequate follow-up (less than 6 months) after surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **170**

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

2008-11-06, 1387/08/16

Ethics committee reference number

EC-87-4278

Health conditions studied

1

Description of health condition studied

Otosclerosis

ICD-10 code

H80.0

ICD-10 code description

Otosclerosis involving oval window, nonobliterative

Primary outcomes

1

Description

hearing results

Timepoint

before operation -6 months after operation

Method of measurement

pure tone audiometry

Secondary outcomes

empty

Intervention groups

1

Description

stapedotomy with polycell prosthesis in control group

Category

Treatment - Surgery

2

Description

stapedotomy with Big Easy Piston prosthesis in interventional group

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dastgheib Hospital

Full name of responsible person

Mohammad Faramarzi

Street address

Next to National Garden-Hafez Street, Shiraz

City

Shiraz

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

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Otolaryngology, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Faramarzi

Position

Associate Professor of Otolaryngology

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