

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison hearing result between fluoroplastic (Teflon) Causse Loop Piston and titanium Soft Clip in patient underwent stapedotomy in 2015 in Dastgheib university Hospital

Protocol summary

Summary

This is an interventional study. Goal of study is comparing hearing improvement in patients with otosclerosis who underwent primary stapedotomy with teflon-piston or softclip prosthesis. This is a randomized controlled trial in a single center (Dastgheib hospital) which is not blind. Statistician does not know which prosthesis was used for each patient. Study population is 120 patients divided in two groups by block randomization; 63 patients in teflon piston group and 57 patients in soft clip group. 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. preoperative physical exam and audiometry will be done for all patients. All operations will be done by one surgeon, under local anesthesia, and with transcanal approach. Patients will be followed at least 6 months. Data gathering will be done between July 2015 and July 2016. In 6 months postoperative follow up physical exam and audiometry will be done. Preoperative and postoperative air conduction (AC) and bone conduction (BC) values at 500, 1000, 2000, 3000 Hz will be recorded. Air-bone gap will be calculated. Speech reception threshold (SRT) and speech discrimination score (SDS) is recorded too. To compare hearing improvement in two groups as primary outcome, these preoperative and postoperative audiometric findings will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012115496N5**

Registration date: **2015-09-11, 1394/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-11, 1394/06/20

Registrant information

Name

Sareh Roosta

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5323

Email address

namazi_balini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

shiraz university of medical science

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison hearing result between fluoroplastic (Teflon)

Causse Loop Piston and titanium Soft Clip in patient underwent stapedotomy in 2015 in Dastgheib university Hospital	2015-06-10, 1394/03/20 Ethics committee reference number IR.sums.med.rec.1394.18
Public title comparing hearing result between two prosthesis teflon-piston and softclip Purpose Treatment Inclusion/Exclusion criteria inclusion criteria:patients who suffered from otosclerosis and underwent stapedotomy with fluoroplastic (teflon) Causse Loop Piston prosthesis or titanium soft clip. 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: 120 Randomization (investigator's opinion) Randomized Randomization description Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features	Health conditions studied <u>1</u> Description of health condition studied otosclerosis ICD-10 code H80.0 ICD-10 code description Otosclerosis involving oval window, nonobliterative Primary outcomes <u>1</u> Description ABG(air-bone gap) Timepoint preoperative and 6 month postoperative Method of measurement audiometry(gap between air and bone conduction) <u>2</u> Description SRT(speech reception threshold) Timepoint preoperative and 6 month postoperative Method of measurement audiometry <u>3</u> Description SDS(speech discrimination score) Timepoint preoperative and 6 month postoperative Method of measurement audiometry
Secondary Ids empty Ethics committees	Secondary outcomes empty
<u>1</u> Ethics committee Name of ethics committee ethics committee of Shiraz University of Medical Sciences Street address Shiraz University of Medical Sciences, Zand Street, Shiraz, Fars, Iran, Islamic Republic City shiraz Postal code 713451978 Approval date	Intervention groups <u>1</u> Description stapedotomy with Flouroplastic(teflon) cause loop piston prosthesis in intervention group 1 Category Treatment - Surgery <u>2</u> Description stapedotomy with titanium soft clip prosthesis in

intervention group 2
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid dastqeib hospital

Full name of responsible person

mohamad faramarzi , otolaryngologist , fellowship of otology , fellowship of rhinology and sinus

Street address

next to melli garden , hafez avenue , 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

Basir Hashemi

Street address

Shiraz University of Medical Sciences , Zand Avenue , Shiraz

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

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Position

otolaryngologist

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences , Zand Avenue , Shiraz , Iran

City

shiraz

Postal code

71348-14336

Phone

+98 71 3235 7282

Fax

Email

vcrdep@sums.ac.ir

Web page address

research.sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Mohamad Faramarzi

Position

otolaryngologist , fellowship of otology , fellowship of rhinology and sinus

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences , Zand Avenue , Shiraz , Iran

City

Shiraz

Postal code

71348-14336

Phone

+98 713230541019

Fax

Email

faramarzi@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

shiraz university of medical science

Full name of responsible person

Nafiseh Gilanifar

Position

otolaryngology resident

Other areas of specialty/work

Street address

shiraz university of medical science-zand avenue-
opposite the palestine avenue-Shiraz

City

shiraz

Postal code

71348-14336

Phone

+98 713230541019

Fax

Email

nafisehgilanifar@yahoo.com

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