

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Teflon-piston and titanium soft-clip KURZ prosthesis in hearing improvement and complications of stapedotomy in otosclerosis patients

Protocol summary

Summary

In order to reconstruct sound conducting mechanisms in middle ear and stapedectomy, different prostheses have been used. Teflon piston is one of the most common prosthesis used. Recently Titanium prosthesis are widely accepted in middle ear surgery due to their favorable characteristics such as endurance, low impedance, and being user friendly. This study is designed to compare hearing outcome and complications of teflon piston prosthesis and titanium in stapes surgery. In this study 80 patients with otosclerosis diagnosed in Amir-Alam hospital will be randomly allocated into one of two arms 1) stapedectomy with teflon piston, 2) stapedectomy with titanium soft-clip. For all of the patients thorough history and physical examination in addition to audiologic studies before and 2 months after surgery will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061610041N1**

Registration date: **2012-09-25, 1391/07/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-25, 1391/07/04

Registrant information

Name

Ali Kouhi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 3037

Email address

a-kouhi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-08-01, 1391/05/11

Expected recruitment end date

2013-08-01, 1392/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Teflon-piston and titanium soft-clip KURZ prosthesis in hearing improvement and complications of stapedotomy in otosclerosis patients

Public title

Comparison of stapes surgery outcomes and complications with Teflon-piston and titanium soft-clip KURZ prosthesis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are diagnosed as otosclerosis and accepted surgical treatment. Exclusion criteria: History of previous ear surgery Finding other than otosclerosis during surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street addressKeshavarz Blvd, Ghods Ave, Tehran University of
Medical Sciences**City**

Tehran

Postal code**Approval date**

2012-09-08, 1391/06/18

Ethics committee reference number

91-02-48-18346-64002

Health conditions studied**1****Description of health condition studied**

Otosclerosis

ICD-10 code

H80.1

ICD-10 code description

Otosclerosis involving oval window, obliterative

Primary outcomes**1****Description**

Hearing threshold

Timepoint

before and 2 month after surgery

Method of measurement

Audiometry

Secondary outcomes**1****Description**

Bone conduction threshold

Timepoint

before and 2 month after surgery

Method of measurement

Audiometry

Intervention groups**1****Description**Intervention: Stapedectomy and titanium soft-clip
prosthesis placement**Category**

Treatment - Surgery

2**Description**Control: Stapedectomy and teflon piston prosthesis
placement**Category**

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir-Alam hospital

Full name of responsible person

Ali Kouhi

Street address

North Saadi Ave

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mrs Norouz zadeh

Street address

Keshavarz blvd, Ghods ave

City

Tehran

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

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

Tehran University of Medical Sciences

Full name of responsible person

Ali Kouhi

Position

Assistant Professor

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