Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of Hearing Results in Stapedotomy in Patient With Otosclrosis With and Without Sodium Hyaluronic Gel.

Protocol summary

Study aim

Auditometry comparison in stapedotomy using sodium hyaluronate gel

Design

In this study, 100 patients with otosclerosis who are eligible for inclusion in the study are selected. Participants are randomly divided into intervention and control groups and each code is assigned to hide the intervention group of each participant.

Settings and conduct

Since the adoption of the proposal, autosclerosis patients who were candidates for the action of the stroke, were randomly divided into two groups of hyaluronic acid and control.The randomization method was Block Randomization. The procedure and anesthesia were the same in the two groups. surgeries were conducted in educational hospitals under supervision of Shiraz University of Medical Sciences. All the surgeries were performed by the performer. The assistant co-worker then collected the surgical and auditory information and delivered it to the statistician. The statistics did not know about the procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - All patients with conductive hearing loss due to otosclerosis. - Age between 18 and 60 years - Have at least six months tracking - Exit criteria: - Patients who have osteopedictosis. - Other causes of conductive hearing loss requiring surgery on a tibia such as the Tympanic Sclerosis - Age under 18 and over 60 - Incomplete follow up or less than six months

Intervention groups

The intervention group consisted of 50 patients with otosclerosis who had criteria for entry into the study. in this patients using sodium hyaluronate gel in stapedotomy. The control group also includes 50 patients with otosclerosis who have criteria for entering the study. in this patients using fatty tissue in stapedotomy

Main outcome variables

Stapadotomy by using sodium hyaluronate gel compared to fatty tissue improves auditory results. It also reduces the risk of sensory neural hearing loss following stapedotomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180106038248N1**
Registration date: **2018-01-19, 1396/10/29**
Registration timing: **retrospective**

Last update: **2018-01-19, 1396/10/29**
Update count: **0**

Registration date

2018-01-19, 1396/10/29

Registrant information

Name

Mohammad Ali Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4332 8533

Email address

asadiali977@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Comparison of Hearing Results in Stapedotomy in Patient With Otosclrosis With and Without Sodium Hyaluronic Gel.

Public title

Effectiveness of Sodium hyaluronic gel in improvement of hearing in patient with otosclrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patiant with hearin loss due to otosclerosis Age 18-60 Can be fallowed up for 6 month

Exclusion criteria:

Patient with stapedectomy. Other cause of hearing loss in patient that need stapes surgery. Age under 18 and over 60.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with one person and random numbers 0 to 9.

Blinding (investigator's opinion)

Single blinded

Blinding description

Those who evaluate the outcome That is, the auditory unit and Safety Committee and Data Supervision The type of material used in practice is unaware.

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 blvd

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.SUMS.MED.REC.1395.67

Health conditions studied

1

Description of health condition studied

Otosclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of auditory hearing before and after stapedotomy using sodium hyaluronate gel compared with adipose tissue

Timepoint

audiometery befor and 21 days after surgury

Method of measurement

Audiometery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consisted of 50 patients with otosclerosis who had criteria for entry into the study. in these patients, sodium hyaluronate gel is used in surgery. In this method, during operation, after the prosthesis is applied, about 0.5 cc gels of sodium hyaluronate is injected around the prosthesis to prevent peri-lymph fluid leakage.

Category

Treatment - Surgery

2

Description

Control group: The control group also includes 50 patients with otosclerosis who have criteria for entering

the study. In this method, during operation, after the prosthesis is applied, adipose tissue is used around the prosthesis to prevent peri-lymph fluid leakage.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dastgheyb hospital

Full name of responsible person

Mohammad Faramarzi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Faramarzi

Position

Asistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable