

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of tympanic membrane grafting medial or lateral to malleus handle

Protocol summary

Summary

This single blinded clinical trial which was conducted in Alzahra and Kashani hospitals, begin with 56 chronic otitis media patients with perforated tympanic membranes. Those patients with at least 15 years old, dry ear, no history of Diabetes Mellitus, autoimmune disease, and smoking, included in the study. Exclusion criteria were: no compliance for follow up, beginning of active otorrhea, ear trauma, and upper airway infection. Patients are selected by simple randomized method. 28 patients were allocated in group A and 28 patients in group B by random 2 column tables. All of the patients assign informed consent. The study was approved by Isfahan university of medical sciences ethics committee, Isfahan, Iran. We assert that no financial conflict of interest exists. At the beginning, demographic data (age, sex, past medical history), physical examination and otoscopic parameters are registered in a form. Group A patients have tympanoplasty by tympanic membrane grafting medial to malleus. Group B have graftings in the lateral side of the malleus. Surgery is done under general anesthesia, and the graft tissue is harvested from temporalis fascia in both groups. All of the patients are referred to Otorhinolaryngology clinic for follow up. 3 months after the surgery both groups are examined and tested by audiometry. Success of surgery is defined as complete repair of tympanic membrane, without lateralization, atelectasis, blunting or retraction pocket. Mean air-bone gap before and after tympanoplasty and success rate of tympanoplasty are analyzed with SPSS version 18 by independent T-test, Ki-square, ANCOVA. P-value > 0.05 considered as significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211062106N3**

Registration date: **2012-11-17, 1391/08/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-17, 1391/08/27

Registrant information

Name

Afrooz Eshaghian

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1236 7247

Email address

eshaghian@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of medical sciences

Expected recruitment start date

2011-04-11, 1390/01/22

Expected recruitment end date

2012-11-01, 1391/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of tympanic membrane grafting medial or lateral to malleus handle

Public title

Comparison of tympanic membrane grafting medial or

lateral to malleus handle

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Those patients with dry ear; no history of Diabetes Mellitus, autoimmune disease and smoking.
Exclusion criteria were: no compliance for follow up; beginning of active otorrhea; ear trauma and upper airway infection.

Age
From **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **56**

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

Isfahan University of Medical sciences, Ethics Committee

Street address

Hezar Jarib St, Isfahan

City

Isfahan

Postal code

جمهوری اسلامی ایران

Approval date

2011-04-11, 1390/01/22

Ethics committee reference number

پ 12/8/758

Health conditions studied

1

Description of health condition studied

Success of surgery

ICD-10 code

H66.3

ICD-10 code description

Chronic suppurative otitis media NOS

Primary outcomes

1

Description

Complete repair of tympanic membrane, without lateralization, atelectasis, blunting or retraction pocket

Timepoint

3 months after surgery

Method of measurement

Physical examination

Secondary outcomes

1

Description

Mean air-bone gap

Timepoint

3 months after intervention

Method of measurement

Pure Tone Audiometry

Intervention groups

1

Description

tympanoplasty by tympanic membrane grafting medial to malleus

Category

Treatment - Surgery

2

Description

graftings in the lateral side of the malleus

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences, Vice
Chancellor for research
Full name of responsible person
Dr Peyman Adibi
Street address
Hezar jariib street
City
Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Vice Chancellor
for research

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
Isfahan University of Medical Sciences
Full name of responsible person
Afrooz Eshaghian
Position
MD, Resident of Otolaryngology
Other areas of specialty/work
Street address
Sofe St, Al-Zahra hospital
City
Isfahan
Postal code
Phone
+98 31 1668 2525
Fax
Email
eshaghian@edc.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Ali Taheri Nia
Position
Otolaryngologist
Other areas of specialty/work
Street address
Sofe St, Al-zahra hospital
City
Isfahan
Postal code
Phone
+98 31 1668 2525
Fax
Email
eshaghian@edc.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Afrooz Eshaghian
Position
MD, Resident of Otolaryngology
Other areas of specialty/work
Street address
Sofe St, Al-Zahra hospital
City
Isfahan
Postal code
Phone
+98 31 1668 2525
Fax
Email
eshaghian@edc.mui.ac.ir
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