Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Randomized Controlled Trial Comparing the Success Rate of Fresh and Dried Temporalis Fascia in Myrigoplasty in Patient With Perforated Tympanic Membrane Due to Chronic Otitis Media

Protocol summary

Summary

We performed this randomized clinical trial in order to compare the prognosis and hearing outcomes of those patients with chronic otitis media, aged between 15 and 60, undergoing myringoplasty using wet (soft) or dry (rigid) temporalis fascia. All patients had perforated Tympanic Membrane with no other ear problems. Patient with Cholesteatoma, granulation tissue and tympanic sclerotic plaque in middle ear were excluded from the trial. This was a randomized double-blind clinical trial being performed in Shahid Dastgheib Hospital of Shiraz University of Medical Sciences during a 1–year period including 233 ears undergoing dry (n=116) or wet (n=117) temporalis fascia myringoplasty. The mean speech reception threshold (SRT) and speech-discrimination scores (SDS), air conduction (AC) and bone conduction (BC) at 250, 500, 1000, 2000, 3000 and 4000 Hz as well as Air-Bone Gap (ABG) were recorded and compared between two surgical methods.In this trial, the patients and the physician that followed and examined them after operation were blinded to type of graft that had been used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102411249N1**
Registration date: **2014-02-11, 1392/11/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-11, 1392/11/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

no

Expected recruitment start date

2013-01-04, 1391/10/15

Expected recruitment end date

2013-07-06, 1392/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Controlled Trial Comparing the Success Rate of Fresh and Dried Temporalis Fascia in Myrigoplasty in Patient With Perforated Tympanic Membrane Due to Chronic Otitis Media

Public title

Fresh and Dried Temporalis Fascia in Myrigoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All the 15 to 60 years old patients that have perforated T.M due to COM; Dry and normal ear

mucosa and normal ossicles; Have no other disease. Exclusion criteria: Underlying disease such as: D.M; renal failure; Active COM; Cholesteatoma; granulation tissue and tympanic sclerotic plaque in middle ear; Age: <15 y/o or >60 y/o ; Smokers; Ossicular fixation and/or disruption

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **233**

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
Zand Blvd.

City
Shiraz

Postal code

Approval date
2011-12-29, 1390/10/08

Ethics committee reference number
CT-P-90-1774

Health conditions studied

1

Description of health condition studied
Perforation of tympanic membrane

ICD-10 code
H72.9

ICD-10 code description
Perforation of tympanic membrane, unspecified

Primary outcomes

1

Description
Tympanic Membrane Repair

Timepoint
before intervention ,3 and 6 months after intervention

Method of measurement
Examination

2

Description
air conducting and bone conducting hearing threshold

Timepoint
before intervention, 3 and 6 months after intervention

Method of measurement
audiometry

Secondary outcomes

1

Description
Air-Bone Gap

Timepoint
before intervention,3 and 6 months after intervention

Method of measurement
audiometry

Intervention groups

1

Description
Myringoplasty using dried temporalis fascia. In this method after harvesting temporalis fascia, we let the fascia dry in the room temperature for about 10 minutes . the technique that we used to put the graft in its places was underlay technique.

Category
Treatment - Surgery

2

Description
Myringoplasty using fresh temporalis fascia. In this method we used the graft right after harvesting temporalis fascia. the technique that we used to put the graft in its places was underlay technique.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Datgheib Hospital

Full name of responsible person

Dr Abolhassan Faramarzi
Street address
Hafez Street
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 Basir Hashemi
Street address
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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
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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