

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the effectiveness of tympanoplasty with temporalis fascia and fibrin glue with the routine method of tympanoplasty with temporalis fascia and Gelfoam

Protocol summary

Study aim

Comparing the effectiveness of tympanoplasty with temporalis fascia and fibrin glue with the routine method of tympanoplasty with temporalis fascia and Gelfoam

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 90 patients. Block randomization method in 15 blocks of 6 and randomization.com online software is used to randomize patients.

Settings and conduct

This study is conducted in Amirkabir hospital in Arak city on 90 candidates for tympanoplasty with temporalis fascia. Patients will be divided into intervention and control groups by block randomization method. 45 patients in the intervention group underwent tympanoplasty surgery with temporalis fascia and fibrin glue and 45 patients in the control group underwent tympanoplasty surgery with temporalis fascia and gelfoam by the same surgeon. This study is double-blind and the patient, clinical caregiver, and data analyst will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: partial rupture of the tympanic membrane, age 18 to 60 years. Exclusion criteria: presence of cholesteatoma or other pathology

Intervention groups

In the intervention group, patients will undergo tympanoplasty surgery through the back of the ear using fibrin glue. In the control group, patients will undergo tympanoplasty surgery by the same surgeon through the back of the ear using Gelfoam.

Main outcome variables

The average tone of the pure voice, Graft take rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231214060360N1**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

Registration date

2023-12-25, 1402/10/04

Registrant information

Name

Sanam Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3227 1227

Email address

sanam.askari1402@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of tympanoplasty with

temporalis fascia and fibrin glue with the routine method of tympanoplasty with temporalis fascia and Gelfoam

Public title
Gelfoamless tympanoplasty by the temporalis fascia and fibrin glue versus routine tympanoplasty and Gelfoam

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Partial tearing of the tympanic membrane Age 18 to 60 years
Exclusion criteria:
 Presence of cholesteatoma or other pathology

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study will be done using randomization.com online software and block method. In this way, random sequences are produced in 15 blocks of 6 and patients will be divided into A or B groups based on the order of the generated sequences. Concealment is done by using non-transparent sealed envelopes in such a way that a number of envelopes with aluminum cover are prepared and each of the random sequences created is recorded on a card. The cards are placed in the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. At the start of the study, according to the order of entry of the participants, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding in this study will be double-blind. In this way, patients will not know about the type of surgery performed. Also, the project administrator, who is responsible for evaluating patients and recording information, and the statistical consultant of the project, who is responsible for data analysis, will recognize patients only through groups A and B. Only the project surgeon who is responsible for performing tympanoplasty surgery for the patients will know about the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2023-10-22, 1402/07/30

Ethics committee reference number

IR.ARAKMU.REC.1402.174

Health conditions studied

1

Description of health condition studied

Perforation of tympanic membrane

ICD-10 code

H72

ICD-10 code description

Perforation of tympanic membrane

Primary outcomes

1

Description

Graft take rate

Timepoint

One week, one month and three months after surgery

Method of measurement

Tympanometry

2

Description

The average pure tone of the voice

Timepoint

Before surgery, one week, one month and three months after surgery

Method of measurement

Audiometry

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, patients will undergo tympanoplasty surgery through the back of the ear using Gelfoam by the same surgeon as the intervention group.

Category

Treatment - Surgery

2

Description

Intervention group: In the intervention group, patients will undergo tympanoplasty surgery through the back of the ear using fibrin glue by the same surgeon as the control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Sanam Asgari

Street address

Shahid Shiroudi st., Parastar sq.

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3819693181

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amirkabir-hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davoud Hekmatpou

Street address

Payambar-e-azam complex, Sardasht Town

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Sanam Asgari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available