Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of tympanoplasty with and without PRF on graft success in patients at high risk of graft failure

Protocol summary

Study aim
The aim of this study is to compare the effectiveness of tympanoplasty with platelet-rich fibrin (PRF) versus standard tympanoplasty in patients at high risk of graft failure.

Design
This is a randomized, single-center, parallel-group controlled clinical trial conducted on 60 patients, with 30 participants allocated to each group. Randomization is performed using block randomization based on a random number table.

Settings and conduct
This single-center clinical trial is conducted at Taleghani Hospital. Platelet-rich fibrin (PRF) is prepared from autologous blood according to a standard protocol. Patients are followed at the first and third months after surgery to assess tympanic membrane healing, post-operative infection, and audiometric outcomes. Outcome assessment is performed by assessors blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria are adults aged 18–65 years with chronic otitis media and at least one risk factor for graft failure. Exclusion criteria include active ear infection, cholesteatoma, or congenital ear anomalies.

Intervention groups
The intervention group undergoes underlay tympanoplasty using temporalis fascia with platelet-rich fibrin (PRF) placed over the graft. The control group receives underlay tympanoplasty with temporalis fascia without PRF.

Main outcome variables
Tympanic membrane graft success; post-operative infection rate; changes in audiometric hearing thresholds.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240519061839N1**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date
2026-04-29, 1405/02/09

Registrant information

Name
Mohammad soheil Hemmat esfeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-14, 1404/11/25

Expected recruitment end date
2026-07-16, 1405/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of tympanoplasty with and without PRF on graft success in patients at high risk of graft failure

Public title
Effect of Using PRF on the Outcome of Tympanic Membrane Repair Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18-65 years with a history of Chronic Otitis Media (COM) Patients with at least one risk factor for graft failure Diabetes (controlled or uncontrolled) Long-term smoking history (at least 10 cigarettes per day for more than 5 years) Immunodeficiency (e.g., long-term treatment with steroids or other immunosuppressive drugs) History of failed tympanoplasty surgery (at least one previous unsuccessful tympanoplasty) Tympanic membrane perforation larger than 50% of the membrane surface History of recent active otorrhea (at least once in the past 3 months) with dry ear for at least 3 weeks before surgery Eustachian tube dysfunction
Exclusion criteria:
Active ear infection (persistent otorrhea or resistant otorrhea at the time of surgery) Presence of cholesteatoma or internal mastoid complications Congenital anomalies of the ear (e.g., ossicular chain malformations or canal anomalies)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to either the tympanoplasty with PRF group or the tympanoplasty without PRF group using block randomization, with blocks generated from a random number table. This method ensures approximately equal numbers of participants in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blind trial. Participants are unaware of their group allocation. Outcome assessors, including those evaluating graft uptake, postoperative infection, and audiometric results, are also blinded to group assignment. The surgeon performing the procedure is not blinded due to the nature of the intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi Street, Daneshjoo Boulevard, Shahriari Square, Velenjak, Shahid Beheshti University of Medical Sciences
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Approval date
2025-12-20, 1404/09/29
Ethics committee reference number
IR.SBMU.MSP.REC.1404.622

Health conditions studied

1

Description of health condition studied
Tympanic Membrane Perforation
ICD-10 code
H72
ICD-10 code description
Perforation of tympanic membrane

2

Description of health condition studied
Chronic Otitis Media
ICD-10 code
H66.1
ICD-10 code description
Chronic tubotympanic suppurative otitis media

Primary outcomes

1

Description
Graft success rate (tympanic membrane graft uptake)
Timepoint
The size of the tympanic membrane perforation will be assessed by otoscopy at baseline, and graft uptake will be compared at 1- and 3-month follow-ups after the intervention.
Method of measurement
Otosopic examination

Secondary outcomes

1

Description
Postoperative infection rate
Timepoint
1, 3 months after surgery
Method of measurement
Physical examination, otoscopy, and evaluation of clinical signs of infection

2

Description
Hearing status
Timepoint
measuring the Air-Bone Gap at baseline and at 1- and 3-month follow-ups after the intervention
Method of measurement
Pure Tone Audiometry

Intervention groups

1

Description
Intervention group:Participants undergo tympanoplasty using temporalis fascia with the underlay technique. Platelet-rich fibrin (PRF, used as an adjunct to reinforce the temporalis fascia graft) is prepared from autologous venous blood by collecting 10 to 15 milliliters in tubes without anticoagulant, followed by centrifugation at 2700 revolutions per minute for 12 minutes. The middle layer containing the PRF clot is extracted, compressed into a membrane, and placed over the temporalis fascia graft after graft positioning.
Category
Treatment - Surgery

2

Description
Control group: Participants undergo standard tympanoplasty using temporalis fascia with the underlay technique without the use of platelet rich fibrin. The temporalis fascia graft is harvested and placed in the tympanic membrane using the conventional underlay method without any adjunctive biological material.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Behrouz Barati
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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behrouz Barati

Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
Due to ethical considerations, patient privacy concerns, and the limited sample size of the study, there is no plan to share deidentified individual participant data. Data will be used solely for the purposes of this study.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Clinical Study Report of Tympanoplasty With and Without PRF Final study report including study design, methodology, outcome measures, and aggregated results. No individual participant data will be shared.
When the data will become available and for how long
The clinical study report will be made available after publication of the study results, for a period of up to 5 years.
To whom data/document is available
The clinical study report will be available to researchers upon reasonable request.
Under which criteria data/document could be used
Access to the data and documents will be granted for academic and research purposes only, following submission of a reasonable request and approval by the principal investigator. No commercial use is permitted.
From where data/document is obtainable
Data and documents can be obtained by contacting the principal investigator via institutional email after approval of the request.
What processes are involved for a request to access data/document
Researchers should submit a written request describing

the purpose of data use. Requests will be reviewed by the principal investigator, and access will be granted if approved.

Comments

There is no further information.