Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Randomized clinical trial; patients with tympanic membrane perforation, effect of Platelet-Rich Fibrin versus no PRF on graft uptake and hearing improvement after tympanoplasty using temporalis fascia graft.

Protocol summary

Study aim

Comparison of tympanoplasty outcomes using temporalis fascia graft alone versus temporalis fascia graft combined with PRF in patients referred to Baqiyatallah Hospital.

Design

This study is a randomized single-blind clinical trial (the surgeon is aware of the clinical procedure and PRF preparation, while the patients are blinded to the type of intervention). Patient allocation to groups is performed using block randomization; the first patient is assigned to group one, the second to group two, and so on until the groups are completed

Settings and conduct

Patients aged 15–65 years undergoing tympanoplasty at Baqiyatallah Hospital will be followed at 1 week, 1 month, and 3 months for assessment of graft healing, hearing, and complications.

Participants/Inclusion and exclusion criteria

Patients aged 15–65 years Inclusion criteria: 1. Central tympanic membrane perforation larger than 25%. 2. No middle ear involvement on temporal bone CT. 3. No scutum erosion on CT scan. 4. Air–bone gap on audiogram less than 40 dB. 5. No active fungal otorrhea. Exclusion criteria: 1. Lack of consent to participate in the study. 2. Immunodeficiency. 3. Chronic diseases requiring corticosteroid therapy. 4. Nasal polyposis and chronic rhinosinusitis (CRS).

Intervention groups

After allocation, patients will undergo tympanoplasty. The surgical procedure is identical in both groups, except that in the intervention group, PRF is used as an adjunct to accelerate the healing process. PRF is obtained from the patient's own blood and, after processing with a specialized device, is applied to the surgical site. In the control group, the tympanic membrane is repaired using temporalis fascia alone.

Main outcome variables

TM closure at 3 months; PTA change and ABG reduction at 3 months; complications (infection, graft necrosis, revision); healing time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240108060650N2**
Registration date: **2025-09-05, 1404/06/14**
Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**
Update count: **0**

Registration date

2025-09-05, 1404/06/14

Registrant information

Name

Keyarmin Ghavam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 8140

Email address

kagh7495@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial; patients with tympanic membrane perforation, effect of Platelet-Rich Fibrin versus no PRF on graft uptake and hearing improvement after tympanoplasty using temporalis fascia graft.

Public title

Evaluation of the Effect of Platelet-rich Fibrin on the Outcomes of Tympanoplasty Using Temporalis Fascia Graft: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Central tympanic membrane perforation larger than 25%. 2. No middle ear involvement on temporal bone CT. 3. No scutum erosion on CT scan. 4. Air–bone gap on audiogram less than 40 dB. 5. No active fungal otorrhea.

Exclusion criteria:

1. Lack of consent to participate in the study 2. Immunodeficiency 3. Chronic diseases requiring corticosteroid therapy 4. Nasal polyposis and chronic rhinosinusitis (CRS)

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization was used, with the individual patient as the randomization unit. The random sequence was generated using statistical software (e.g., Random Allocation Software) with variable block sizes of 4 and 6 to minimize predictability. The sequence list was prepared by an independent researcher and placed in opaque, sealed, and sequentially numbered envelopes. Upon patient enrollment, the corresponding envelope was opened and the patient was allocated to the respective group. This ensured proper allocation concealment, with both investigators and patients blinded to the assignment until the moment of allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

This trial is conducted as a single-blind study. In this design, patients are blinded to the type of intervention (use or non-use of PRF). Although the surgeon is necessarily aware of group allocation due to the nature of the procedure, outcome assessments (tympanic membrane examination and audiometric testing) are performed by an independent evaluator blinded to the intervention. In addition, data analysis is conducted by a statistician who remains unaware of the group assignments. Thus, patients, the outcome assessor, and the data analyst are blinded, while only the surgeon is aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah of medical sciences

Street address

Molla Sadra Street, at the intersection with Sheikh Bahayi

City

tehran

Province

Tehran

Postal code

1435916471

Approval date

2025-08-05, 1404/05/14

Ethics committee reference number

IR.BMSU.REC.1404.042

Health conditions studied

1

Description of health condition studied

tympanic membrane perforation

ICD-10 code

H72.0

ICD-10 code description

Central perforation of tympanic membrane

Primary outcomes

1

Description

hearing threshold

Timepoint

At 1 month and 3 months follow-up

Method of measurement

audiometric testing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, following tympanoplasty with temporalis fascia graft, PRF is used as an adjunct to accelerate the healing process. PRF is obtained from the patient's own blood and, after processing using a specialized device, is applied to the surgical site.
Category
Treatment - Surgery

2

Description
Control group: In the control group, the tympanic membrane is repaired using temporalis fascia alone.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Masoume saeedi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mahdieh Hasanalifard
Street address
Baqiyatallah al-Azam Hospital, Molla Sadra St., after Sheikh Bahayi St., Vanak Square, Tehran, Iran.
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Keyarmin Ghavam
Position
ENT specialist
Latest degree
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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