

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Molla Sadra Street, at the intersection with Sheikh Bahayi

City

tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8805 0435

Email

bag@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mahdieh Hasanlifard

Street address

Baqiyatallah al-Azam Hospital, Molla Sadra St., after Sheikh Bahayi St., Vanak Square, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0435

Email

hasanalifardm@gmail.com

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

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Eisargaran Shomali, Farhang 3rd, No. 14

City

Tehran

Province

Tehran

Postal code

1981776397

Phone

+98 21 2213 4625

Email

kagh7495@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

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Person responsible for updating data**Contact****Name of organization / entity**

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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