Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of PRP-enriched Gelfoam and Conventional Gelfoam on the Healing of Chronic Tympanic Membrane Perforation; A Double-blind Randomized Clinical Trial

Protocol summary

Summary

In the present study we aim to evaluate the effect of PRP-enriched gelfoam on the healing of chronic TM perforation in comparison with gelfoam alone. In this Double-blind randomized clinical trial Patients with chronic tympanic membrane rupture attending to Otolaryngology clinic with ages between 18 and 60 years old who are candidates for type I Tympanoplasty will be enrolled in the study. Patients with active otorrhea, cholesteatoma, canal stenosis, TM perforation more than 5 mm, autoimmune and hematologic diseases, active neoplasm, immunosuppressive treatment and diabetes as well as smokers will be excluded from the study. Patients will be randomly allocated to two groups; intervention group will undergo Tympanoplasty with platelet rich plasma (PRP)-enriched gel foams and control group will undergo operation with conventional gel foams alone. In the first post operational visit, three days after intervention, wound dressing and mesh were disposed. Patients' information was recorded 2 and 3 months after surgery and underwent analysis by a statistician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083017413N16**
Registration date: **2016-09-12, 1395/06/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-12, 1395/06/22

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of PRP-enriched Gelfoam and Conventional Gelfoam on the Healing of Chronic Tympanic Membrane Perforation; A Double-blind Randomized Clinical Trial

Public title

Evaluating effect of PRP-enriched gelfoam on healing of Tympanic membrane rupture

Purpose

Treatment

Inclusion/Exclusion criteria

patients with ages between 18 and 60 years old who

were candidates for type I Tympanoplasty were enrolled in the study. Patients with active otorrhea, cholesteatoma, canal stenosis, TM perforation more than 5 mm, autoimmune and hematologic diseases, active neoplasm, immunosuppressive treatment and diabetes as well as smokers were excluded from the study.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

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
Baqiyatallah University of Medical Sciences

Street address
Nosrati Alley, Sheykh Bahaei Street, Mollasadra street, Vanaq Square, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-10-26, 1394/08/04

Ethics committee reference number
IR.BMSU.REC.194.168

Health conditions studied

1

Description of health condition studied
Tympanic Membrane Perforation

ICD-10 code
H72

ICD-10 code description
Perforation of tympanic membrane

Primary outcomes

1

Description
Healing of Tympanic Membrane

Timepoint
2 and 3 months after intervention

Method of measurement
Hook tool

2

Description
Tympanic Membrane Rupture

Timepoint
Before Intervention

Method of measurement
Hook tool

Secondary outcomes

1

Description
Side Effects

Timepoint
2 and 3 months after intervention

Method of measurement
History and Examination

2

Description
Treatment Cost

Timepoint
After Intervention

Method of measurement
Receipt

Intervention groups

1

Description
After transferring the patient to operation room and before presence of surgeon, 8 ml of blood will be obtained from patient’s brachial vein in intervention group and will be stored in PRP kits (RegenKit BCT). Samples will be centrifuged in room’s temperature by 3000 rounds/min in 5 minutes then 3 ml of the resulting solution will be disposed from the top of the kit. Based on factory’s instruction, the remaining solution will be shaken for obtaining 1ml of high density and homogenous PRP. In the following, small (1 and 2- mm) and two large (1 to 2 mm more than size of perforation) gel foams will be prepared and enriched with PRP in galipot. In control group gel foams will be impregnated with normal saline for blinding purpose. Then surgeon, who is not aware of added material to gel foams, will be paged to the OR. After convenient prep and drep 1 ml of Lidocaine 2% will be injected to ear canal using insulin

syringe. Following anesthesia, sharp rosen will be used for trimming of TM perforation margins and gel foams will be put in the middle ear. Then one of the large gel foams will be located in middle ear, under TM, and another one will be fixed in ear canal on the TM. Ear canal will be filled with small gel foams and Tetracycline mesh and wound dressing will be done using one gauze and surgifix. After operation, patients will be visited in recovery room and will be discharged with oral cephalexin.

Category

Treatment - Surgery

2

Description

After transferring the patient to operation room and before presence of surgeon, small (1 and 2- mm) and two large (1 to 2 mm more than size of perforation) gel foams will be prepared and will be impregnated with normal saline for blinding purpose. Then surgeon, who is not aware of added material to gel foams, will be paged to the OR. After convenient prep and drep 1 ml of Lidocaine 2% will be injected to ear canal using insulin syringe. Following anesthesia, sharp rosen will be used for trimming of TM perforation margins and gel foams will be put in the middle ear. Then one of the large gel foams will be located in middle ear, under TM, and another one will be fixed in ear canal on the TM. Ear canal will be filled with small gel foams and Tetracycline mesh and wound dressing will be done using one gauze and surgifix. After operation, patients will be visited in recovery room and will be discharged with oral cephalexin.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohammad Hossein Khosravi

Street address

Baqiyatallah Hospital, Mollasadra st., Vanaq sq., Tehran, Iran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq., Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baqiyatallah 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

Name of organization / entity

Students' Research Committee, Baqiyatallah University of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

Secretary-General

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Mohammad Hossein Khosravi

Position

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Other areas of specialty/work

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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