

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of tympanoplasty results using gelfoam block support, autologus fat blocks and mix of fat and gelfoam blocks in Chronic Otitis Media: A Clinical Trial studyI

Protocol summary

Study aim

Comparison of tympanoplasty results using gelfoam block support, autologus fat blocks and mix of fat and gelfoam blocks in Chronic Otitis Media

Design

A controlled randomized trial. double-blind with a parallel groupe design of 96 patients(phase 3)

Settings and conduct

According to the patient group based on randomization, on the graft and in the area of the perforation connection with the graft in groups A, B, and C, respectively, gelfoam, fat, and the combination of gelfoam and fat pressed together are used. The place of operation is Amir al-Momenin Hospital in Rasht city, Gilan province.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic otitis media with simple TM perforation and the age range of 18 to 65 years Exclusion criteria: 1. ABG > 40 db 2.Ossicular disorders 3. Evidence of cholesteatoma 4. Complete perforation without edge (at least 2 mm) TM 5. Active otorrhea during the recent a month 6. Presence of large and thick plaques of tympanosclerosis in the edges of perforation 7. underlying diseases such as diabetes, hypothyroidy, severe uremia, bleeding diseases, immunodeficiency diseases, 8. smoking 9. Evidence in favor of Eustachian tube disorder, such as bilateral perforation, bilateral otorrhea, atelectatic ears, etc

Intervention groups

Placement of graft by underlay method and middle ear pack in all 3 groups with gelfoam for graft support and then according to the patient group based on randomization, on the graft and in the area of the perforation junction with the graft in Groups A, B, and C, respectively, gelfoam, fat, and the combination of gelfoam and fat are pressed, it is used, and the external ear canal is packed with gelfoam in all 3 groups.

Main outcome variables

Surgical success rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220608055103N1**

Registration date: **2022-10-04, 1401/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-04, 1401/07/12**

Update count: **0**

Registration date

2022-10-04, 1401/07/12

Registrant information

Name

Shadman Nemati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3322 5242

Email address

drshadmannemati_ent@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-03-17, 1401/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of tympanoplasty results using gelfoam block support, autologus fat blocks and mix of fat and gelfoam blocks in Chronic Otitis Media: A Clinical Trial studyl

Public title

tympanoplasty results using gelfoam block , autologus fat and mix of fat and gelfoam in Chronic Otitis Media

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with chronic otitis media with simple TM perforation and the age range of 18 to 65 years

Exclusion criteria:

ABG > 40 db ossicular disorders Evidence of cholesteatoma Complete perforation without edge (at least 2 mm) TM Active otorrhea during recent a month Presence of large and thick plaques of tympanosclerosis in the edges of perforation underlying diseases such as diabetes, hypothyroidy, severe uremia, bleeding diseases, immunodeficiency diseases smoking Evidence in favor of Eustachian tube disorder, such as bilateral perforation, bilateral otorrhea, atelectatic ears, etc

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation in 3 groups is based on random blocks, the sequence of which will be determined based on Table of random numbers. The list of this sequence of samples in 3 groups will be kept in the ENT research center in a sealed envelope and will be read gradually after the start of the study based on the inclusion criteria of the patients. Then, according to the patient group based on randomization, on the graft and in the area of the perforation connection with the graft, gelfoam is used in group A, and fat block in group B, and the combination of gelfoam and fat block pressed together is used in group C. The external ear canal is packed by Gelfoam in all 3 groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of random allocation in 3 groups is based on random blocks, the sequence of which will be determined based on Table of random numbers. The list of this

sequence of samples in 3 groups will be kept in the ENT research center in a sealed envelope and will be read gradually after the start of the study based on the inclusion criteria of the patients. After collecting the patients according to the random block, the participants are assigned to one of the groups A to c. Patients are not aware of their allocation to treatment groups. Based on the group mentioned in the received envelope, the treating doctor performs one of the treatment measures for the patient. The evaluation of the eardrum transplant result is done one month later by a specialist assistant who The patients are unaware of the therapeutic action taken. The follow-up of the patients is carried out for up to one month by the attending physician who is not aware of the therapeutic action taken.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی گیلان

Street address

Amiralmomenin Hospital, 17 shahrivar street, bank melli square

City

rasht

Province

Guilan

Postal code

4139638459

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.GUMS.REC.1401.104

Health conditions studied**1****Description of health condition studied**

Chronic Otitis Media

ICD-10 code

H72.0

ICD-10 code description

Central perforation of tympanic membrane

Primary outcomes**1****Description**

Link success rate

Timepoint
before surgery and 3 months after surgery

Method of measurement
Pure tone audiometry at frequencies of 512, 1024, 2048 Hz is used to measure ABG, and tympanogram and the amount and location of its peak (types A, B, C) are used to check the health of the new tympanic membrane.

Secondary outcomes

1

Description
(ABG rate) air bone gap

Timepoint
before surgery and 3 months after surgery

Method of measurement
Pure tone audiometry at frequencies of 512, 1024, 2048 Hz is used to measure chatter, and tympanogram and the amount and location of its peak (types A, B, C) are used to check the health of the new tympanic membrane.

Intervention groups

1

Description
Intervention group: , gelfoam is used in group A.

Category
Treatment - Surgery

2

Description
Intervention group: Fat block is used in group B.In order to prepare fat blocks, about 0.5 to 1 cubic centimeter is removed from the same place of skin incision and from the fat under the skin, and it is pressed and dried by Fat Presser

Category
Treatment - Surgery

3

Description
Intervention group: In group C, a combination of gelfoam and fat block pressed together is used. In this group, along with the piece of fat, the same amount of Gelfoam is placed in the Fat Presser and they are pressed and dried together.Then they are cut into blocks and small pieces of 2 x 3 mm by a surgical knife.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person
Dr.shadman nemati

Street address
.17 shahrivar street, bank melli square,
Amiralmomenin Hospital

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Rasht

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4139638459

Phone
+98 13 3322 5242

Email
drshadmannemati_ent@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
دکتر محمد رضا نقی پور

Street address
خیابان نامجو، خیابان شهید سیادت، روبروی بیمارستان 17 شهرپور

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Rasht university of medical science

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
Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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

Rasht University of Medical Sciences

Full name of responsible person

dr. malihe akbarpour

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In the case of individual patients data, all potential data will be shared after de-identifying individuals. The result of the clinical study will be published in the form of an article

When the data will become available and for how long

The access period starts 6 months after publication of the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

for secondary data analysis and meta-analysis

From where data/document is obtainable

Dr. shadman nemati, Otorhinolaryngology Research Center. Amiralmomenin Hospital , 17 Shahrivar Street. Bank Melli Square. Rasht. Postal code: 4139638459 -Tell: 01333225242- Mobile: 09111370488- Email: drshadmannemati_ent@yahoo.com

What processes are involved for a request to access data/document

After receiving the applicant's request and a brief statement of the protocol in which the mentioned information is used, a Preliminary review will be done and the information will be sent to the researcher within 2 weeks

Comments