

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the results of middle ear packing using Gelfom in comparison with silastic sheet in the treatment of timpanoplasty

Protocol summary

Study aim

The aim of this study is comparing the result of cartilage tympanoplasty using two packing materials : silastic sheet and gelfoam.

Design

78 patients will undergo cartilage tympanoplasty in Imam Khomeini hospital during 2017-2018. The surgeon will fill a questionnaire for each patients which contains demographic questions, symptoms and position of the tympanic membrane. then, patients will be divided into two groups (silastic sheet or gelfoam) using the random numbers table.

Settings and conduct

This study is conducted in the Valiasr hospital. Patients referred to Ear, Nose and Throat clinic will be separated into 2 groups if they meet the inclusion criteria. In our study, the patients, the surgeon (until the moment of surgery) and the statistician will be blind.

Participants/Inclusion and exclusion criteria

All patients who are candidate for COM unilateral cartilage tympanoplasty during the time of our study are included in the study. All patients will sign a written consent form. Patients with history of sensory-neural hearing loss, history of anatomic disorders of auditory system, history of otorrhea in the last 3 months and patients who must undergo mastoidectomy are excluded from this study. All patients are free to leave the study and this will not affect the course of their treatment.

Intervention groups

There are 2 intervention groups in the current study. First group includes patients with perforated tympanic membrane who will undergo cartilage tympanoplasty using Gelfoam. Second group of these patients will undergo the same surgery using Silastic sheet.

Main outcome variables

The main outcome of this study is to evaluate the results of tympanoplasty by measuring the graft take, anatomic position of the graft and hearing improvement and comparing the outcomes in Gelfoam of silastic sheet

groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171004036554N2**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

Hamed Emami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2393

Email address

h_emami@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the results of middle ear packing using Gelfom in comparison with silastic sheet in the treatment of tympanoplasty

Public title

Evaluation of the results of using two packing techniques in the repair of perforated tympanic membrane

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients who are candidate of COM unilateral cartilage tympanoplasty patients who volunteer to participate in this study

Exclusion criteria:

History of sensory-neural hearing loss History of anatomic disorder of auditory system Patients who must undergo mastoidectomy Anterior perforation of TM history of otorrhea in the last 3 months

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized clinical trial which uses blocking technique. Each block contains 4 patients, as a result 20 arrangements are possible. In selection of blocks, table of randomizes numbers is used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The surgeon is not informed of the surgical technique until the middle of surgery when the packing material is delivered to the surgical team. Evaluation of results and examination of patients is performed by a second surgeon 3 months after the surgery. Therefore the surgeon is blind to the technique until the moment of surgery. Statistician and the patients are also blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Central department of Tehran University of Medical Sciences, Intersection of Keshavarz blvd. and Qods St. , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4083

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

Repairing techniques in perforated tympanic membrane

ICD-10 code

H72

ICD-10 code description

Perforation of tympanic membrane

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

Graft take

Timepoint

3 months after the surgery

Method of measurement

physical examination using a microscope by the the surgeon

2**Description**

Hearing improvemnt

Timepoint

3 month after the surgery

Method of measurement

Audiometry

3**Description**

Anatomical position
Timepoint
3 months after the surgery
Method of measurement
physical examination using a microscope by the the surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cartilage tympanoplasty using Gelfoam

Category

Treatment - Surgery

2

Description

Intervention group 2: Cartilage tympanoplasty using Silastic sheet

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr. Hamed Emami

Street address

Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

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1419733141

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entrc@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamad Ali Sahraian

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Vice chancellor for research, Central department of Tehran University of Medical Sciences, Intersection of Keshavarz Blvd. and Qods St.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

ایلناز کاظمی

Position

Resident of otorhinolaryngology

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hamed Emami

Position

Assistant 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)

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

Not applicable

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