Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Tympanoplasty success in draining ear by using wet or dry fascia

Protocol summary

Summary

This randomized prospective study will be carried out on patients who underwent tympanoplasty and mastoidectomy. The patients who complied with the study criteria will be randomly assigned to receive a wet graft or a dry graft. The study consists of 40 ears which will be assigned into the following groups. Audio-tympanometry will be done for all the patients and all the operations will be performed under general anesthesia, using a post-auricular approach. The temporalis fascia of the patients undergoing the dry graft procedure will be immediately removed after the post-auricular incision. It will be then placed and spread between glass plates and dried until it becomes rigid. The temporalis fascia of the patients undergoing the wet graft operation will be removed and spread between glass plates immediately before placing graft. Before the placement of the graft, using the underlay technique, the samples of both wet and dry grafts will be taken for histological examination. All the patients received postoperative oral antibiotics for10 days. The deep external auditory canals will be cleared of serosanguinous collections and an absorbable gelatin sponge. Graft condition will be assessed in that time by an examiner, who is blind of graft type, using autoscope or microscope.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012294455N2**
Registration date: **2011-02-06, 1389/11/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-02-06, 1389/11/17

Registrant information

Name

Samad Ghiasi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 3886

Email address

ghiasis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-12-31, 1389/10/10

Expected recruitment end date

2011-03-01, 1389/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tympanoplasty success in draining ear by using wet or dry fascia

Public title

Tympanoplasty success in draining ear by using wet or dry fascia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age at least 12 years old, indication of middle ear surgery and tympanic membrane surgery, Draining ear after medical therapy, Interest for corporation in this study, Referring to Oto-rhinolaryngology and Head and Neck Surgery, clinic in Imam Reza (Training and Research Hospital), follow-up

for a minimum period of 2 months Exclusion criteria: previous middle ear surgery, ears tumor with chronic granular myringitis, presence of cancer, diabetes mellitus, or renal failure

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics committee, Tabriz University of Medical Sciences

Street address
Ethics committee, Tabriz University of Medical Sciences, Daneshgah Street

City
Tabriz

Postal code

Approval date
2010-12-30, 1389/10/09

Ethics committee reference number
8948

Health conditions studied

1

Description of health condition studied
Chronic otitis media

ICD-10 code
H71

ICD-10 code description
Cholesteatoma of middle ear

Primary outcomes

1

Description
Success rate

Timepoint
2 months

Method of measurement
exammination-observation

Secondary outcomes

1

Description
microscopic appearance

Timepoint
A few days after surgery

Method of measurement
Microscopic examination

Intervention groups

1

Description
The temporalis fascia of patients undergoing the dry graft procedure will be removed immediately after the postauricular incision. It will be then placed and spread between glass plates and dried until it becomes rigid.

Category
Treatment - Surgery

2

Description
The temporalis fascia of patients undergoing the wet graft operation will be removed and spread between glass plates immediately before placing graft.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Training and Research Hospital

Full name of responsible person
Dr Samad Ghiasi, Assistant Professor of ENT

Street address
ENT ward - Imam Reza hospital- Golgasht

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr Ali Meshkini

Street address

Medical School, Tabriz University Of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Samad Ghiasi

Position

Assistant Professor

Other areas of specialty/work

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ghiasis@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Saman Vegari

Position

Resident of ENT

Other areas of specialty/work

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Web page address

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