Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Clinical application of an amniotic membrane in canal wall down tympanomastoidectomy

Protocol summary

Summary

Aim of this study was comparison of clinical application of an amniotic membrane in canal wall down tympanomastoidectomy in adults regarding primary outcomes. This was a double blind randomized clinical study in a single center in Dastgheib University Hospital (Shiraz-Iran). Audiologist and statistician as assessors were blind. Patients divided in two groups; amniotic membrane (75 patients) and control group (75 patients). Inclusion criteria were: all patients more than 18 years old, canal wall down mastoidectomy because of choronic otitis media with choleastetoma, final size of tympanic membrane perforation more than 50%. Exclusion criteria were: revision surgery, pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic disorder and chronic liver or renal disease, patients without adequate follow up (less than 6 months), canal wall down mastoidectomy because of other reason such as tumors. Primary outcomes were otorrhea, granulation tissue, epithelialization, tympanic membrane graft successes rate and hearing results at least six months was compared within two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081915496N16**
Registration date: **2017-05-07, 1396/02/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-07, 1396/02/17

Registrant information

Name

Sareh Roosta

Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5323

Email address

namazi_balini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical application of an amniotic membrane in canal wall down tympanomastoidectomy

Public title

Clinical application of embryonic membrane in middle ear surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients more than 18 years old; canal wall down mastoidectomy because of choronic otitis media with choleastetoma; final size of tympanic

membrane perforation more than 50%. Exclusion criteria: revision surgery; pre operative medical problems such as asthma, diabetes, coagulation disorders, cardiovascular disease, basic metabolic disorder and chronic liver or renal disease; patients without adequate follow up (less than 6 months); canal wall down mastoidectomy because of other reason such as tumors.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

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 of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Postal code

Approval date
2017-04-19, 1396/01/30

Ethics committee reference number
IR.SUMS.MED.REC.1396.13

Health conditions studied

1

Description of health condition studied
choronic otitis media with choleasteaoma

ICD-10 code
H66.2,H66.

ICD-10 code description
Chronic atticoantral suppurative otitis media, Other chronic suppurative otitis media,Suppurative otitis media, unspecified,Chronic mastoiditis

Primary outcomes

1

Description
tympanic membrane graft successes rate

Timepoint
within 6 months after surgery

Method of measurement
Observation by physician

2

Description
epithelialization

Timepoint
within 6 months after surgery

Method of measurement
Observation by physician

3

Description
otorrhea

Timepoint
within 6 months after surgery

Method of measurement
Observation by physician

4

Description
existance granulation tissue

Timepoint
within 6 months after surgery

Method of measurement
Observation by physician

5

Description
hearing threshold

Timepoint
before operation -6 months after operation

Method of measurement
pure tone audiometry

Secondary outcomes

empty

Intervention groups

1

Description
The aminiotic membrane used for coverage of muscle flap in intervention group.

Category
Treatment - Surgery

2

Description
The aminiotic membrane did not used for coverage of muscle flap in control group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Dastgheib Hospital
Full name of responsible person
Mohammad Faramarzi
Street address
Hafez Street, Next to National Garden
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Shiraz 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
Department of Otolaryngology, Shiraz University of Medical Sciences
Full name of responsible person
Sareh Roosta
Position
MSc of Biostatistics
Other areas of specialty/work
Street address
Department of Otolaryngology, Khalili Hospital, Khalili Street
City
Shiraz
Postal code
Phone
+98 71 3629 1478
Fax
Email
Roosta.Sareh@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Otolaryngology, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Faramarzi
Position
Associate Professor of Otolaryngology
Other areas of specialty/work
Street address
Department of Otolaryngology, Khalili Hospital, Khalili Street
City
Shiraz
Postal code
Phone
00
Fax
Email
Faramarzi@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Otolaryngology, Shiraz University of Medical Sciences
Full name of responsible person
Sareh Roosta
Position
MSc of Biostatistics
Other areas of specialty/work
Street address
Department of Otolaryngology, Khalili Hospital, Khalili Street
City
Shiraz
Postal code
Phone
Fax

Email
Roosta.Sareh@gmail.com
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