

# 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 chronic 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 chronic 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

chronic otitis media with cholesteatoma

#### 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

existence 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 amniotic 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*