Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effect of pre-operation Povidone-iodine irrigation on sensory neural hearing loss in Tympanoplasty

Protocol summary

Study aim

Comparison of the effect of pre-operation irrigation with 5% and 10% Povidone-iodine on sensory neural hearing loss and tympanic membrane repair after Tympanoplasty.

Design

Randomised clinical trial, double-blind, prospective Since there is no similar human study with completely similar results, the sample size in each group will be equal to the minimum number required for parametric tests, with at least 30 individuals in each group.

Settings and conduct

in Shiraz University of medical science in Khalili Hospital. Number of at least 60 patients requiring tympanoplasty will be randomly divided into two groups with the block randomization method according to the percent of betadine used. Since the examining professor and the patient are unaware of the percent of iodine use, the study is double blind.

Participants/Inclusion and exclusion criteria

Patients' inclusion criteria for this study include: 1) Normal mucosa 2) The ear must be dry for at least one month before surgery and must be free of inflammation and infection. 3) The size of the tympanic membrane rupture should be more than 50%. 4) Normal ossicle status of ear. 5) Age must be older than 18 years old 6) Those who do not have cholesteatoma, granulation tissue, and tympanosclerosis plaque. Exclusion criteria for this study include: 1) If the patient does not meet any of the above criteria will be excluded 2) Age under 18 years old 3) Those who got followed up for less than 6 months 4) Smokers, diabetics, liver and kidney failure

Intervention groups

To disinfect the external ear in the first group 5%Betadine and in the second group 10%Betadine will be poured in the ear and will be kept for 5 minutes. Audiometry will be performed one week before surgery and 6 months after surgery That will be analyzed for practice.

Main outcome variables

Graft Success Rate Sensory Neural Hearing Loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046177N1**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**
Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Mohammadreza Khademalizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 5395

Email address

khadem@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of pre-operation Povidone-iodine irrigation on sensory neural hearing loss in Tympanoplasty

Public title
The effect of pre-operation Povidone-iodine irrigation on sensory neural hearing loss in Tympanoplasty

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Normal mucosa The ear must be dry for at least one month before surgery and must be free of inflammation and infection. The size of the tympanic membrane rupture should be more than 50%. Normal ossicle status of ear. Age must be older than 18 years old Those who do not have cholesteatoma, granulation tissue, and tympanosclerosis plaque.

Exclusion criteria:
If the patient does not meet any of the above criteria will be excluded Age under 18 years old Those who got followed up for less than 6 months Smokers, diabetics, liver and kidney failure

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Number of at least 60 patients requiring tympanoplasty will be randomly divided into two groups with the block randomization method according to the percent of betadine used. Given the block size of 2 there are two ways to assign participants to a block. AB or BA. (A) stands for 5% betadine and (B) stands for 10% betadine. Using Microsoft Excel software we will produce 30 numbers equal to the sample size in each group between 0 to 9. For numbers 0, 2, 4, 6, 8 AB combination and for numbers 1, 3, 5, 7, 9 BA combination will be chosen.

Blinding (investigator's opinion)
Double blinded

Blinding description
all patients will undergo surgery by Dr Mohammed Faramarzi consultant professor at Dastgheib and Dena hospital and will be examined by a supervisor professor Dr Mahmoud Shishagar in 1, 2, 3 and 6 months after operation in Khalili hospital and Motahari clinic. Although the first surgeon visits the patients himself but intervenes in completing questionnaire and post operation research process after supervisor professor, not knowing the prep process and betadine percentage. Since the examining professor and the patient are unaware of the percent of iodine use, the study is double blind.

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 Science Central Building, Zand Street

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2019-12-28, 1398/10/07

Ethics committee reference number
IR.SUMS.MED.REC.1398.535

Health conditions studied

1

Description of health condition studied
Sensorineural Hearing Loss

ICD-10 code
H90.5

ICD-10 code description
Unspecified sensorineural hearing loss

Primary outcomes

1

Description
Sensory Neural Hearing Loss

Timepoint
Before Surgery And 6 Month After Surgery

Method of measurement
Pure Tone Audiometry Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To disinfect the external ear 5%Betadine will be poured in the ear and will be kept for 5 minutes. Audiometry will be performed one week before surgery and 6 months after surgery. However the audiometry performed 6 months after surgery will be analyzed for practice.
Category
Treatment - Devices

2

Description
Control group: To disinfect the external ear 10%Betadine will be poured in the ear and will be kept for 5 minutes. Audiometry will be performed one week before surgery and 6 months after surgery. However the audiometry performed 6 months after surgery will be analyzed for practice.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili Hospital
Full name of responsible person
Mohammadreza Khademalizadeh
Street address
ENT Department, Khalili Hospital, Khalili Street
City
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71348-14336
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+98 71 3629 1470
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Shiraz University of Medical Science Central Building, Zand Street
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71348-14336
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ghasemiy@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadreza Khademalizadeh
Position
ENT Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
ENT Department, Khalili Hospital, Khalili Street
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Mohammadreza Khademalizadeh
Position

ENT Resident

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Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

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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

Undecided - It is not yet known if there will be a plan to make this available

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