

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

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Khadem@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity
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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