Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of split-thickness skin grafts on the acceleration of mastidectomy repair along with lowering the posterior wall and comparing it with the control group.

Protocol summary

Study aim
Determining the effect of using skin graft in accelerating mastoidectomy repair by lowering the canal wall and comparing it with the control group.

Design
A clinical trial with a control group with parallel groups, double-blind, simple, randomized, using closed envelopes on 50 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Cholestoma patients in Qaim and Imam Reza Hospital of Mashhad who needed tympanomastoidectomy and CWD (canal wall down)were divided into 2 groups. that in the intervention group, in addition to cwd, STSG was also implanted in the mastoid cavity In this study, except for the surgeon who was not blinded, the rest of the people were blind to the type of group

Participants/Inclusion and exclusion criteria
Inclusion criteria: All cholesteatoma patients who have not yet undergone ear surgery and need CWD surgery
Exclusion criteria: Patients who have brain and nerve complications or have a history of previous surgery

Intervention groups
Intervention: Cholestoma patients who underwent CWD surgery with STSG implantation in the mastoid cavity.
Control: Cholestoma patients who underwent CWD surgery without STSG implantation

Main outcome variables
Mastoid cavity repair, vertigo, hearing loss, otorrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230726058934N1**
Registration date: **2024-01-07, 1402/10/17**
Registration timing: **prospective**

Last update: **2024-01-07, 1402/10/17**
Update count: **0**

Registration date
2024-01-07, 1402/10/17

Registrant information

Name
Mohamadreza Afzalzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-10, 1402/10/20

Expected recruitment end date
2024-01-25, 1402/11/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of split-thickness skin grafts on the acceleration of mastidectomy repair along with lowering the posterior wall and comparing it with the control group.

Public title

Investigating the effect of STSG on Cholesteatoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with Cholesteatoma

Exclusion criteria:

Revision surgery Cns complication

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who are candidates to enter the plan after obtaining consent using closed envelopes, choose one based on group A and group B, who will undergo cwd surgery alone or cwd along with stsg.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were blinded to which group they entered, and patients were told that they could undergo only normal surgery or with stsg. The researcher and the author of the article are blinded to which group A and B belong to the intervention group There was no possibility of blinding the surgeon due to the form of the study, but the evaluations after the operation were performed by a person who was blinded to the patient group. The statistical analyzer was also blinded to the groups

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

East door of university campus, Azadi square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۹۱۹۱۹۱۷۷۸

Approval date

2023-05-09, 1402/02/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.096

Health conditions studied

1

Description of health condition studied

Cholesteatoma

ICD-10 code

H71.2

ICD-10 code description

Cholesteatoma of mastoid

Primary outcomes

1

Description

Mastoid cavity repair rate

Timepoint

One month and 3 months later

Method of measurement

Examination of the ear under a microscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cholestoma patients who undergo mastoidectomy and CWD surgery, at the end of the operation, stsg is removed from the skin behind the canal and expanded in the mastoid cavity.

Category

Treatment - Surgery

2

Description

Control group: Cholestoma patients who undergo mastoidectomy and CWD surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital of Mashhad

Full name of responsible person
Dr mohammadreza afzal zadeh

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Ghaem hospital, Ahmad abad street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mashhad 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
Torbate-Jam University of Medical Sciences

Full name of responsible person
Dr mohammadreza akhoundian yazd

Position
Ent resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available