

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**Investigating the effect of split-thickness skin grafts on the acceleration of mastoidectomy 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 3492

##### Email address

afzalzadehmr@mums.ac.ir

#### 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 mastoidectomy 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**  
9919191778  
**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

**Street address**

Ghaem hospital, Ahmad abad street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3840 0000

**Email**

b.ghaem@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Mashhad medical universty,Vakil abad street

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mashhad

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9137913131

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+98 51 3879 5031

**Email**

presidentoffice@mums.ac.ir

**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

**Street address**

Ghaem hospital, Ahmad abad street

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**Province**

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**Phone**

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akhoundianm911@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr mohammadreza afzal zadeh

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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Ghaem hospital ,Ahmad abad street

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**Province**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Torbate-Jam University of Medical Sciences

**Full name of responsible person**

Dr mohammadreza akhoundian yazd

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Ent resident

**Latest degree**

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**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3840 0000

**Email**

akhoundianm911@gmail.com

**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