

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of residual cholesteatoma in two methods of tympanomastoidectomy CWD and ICW with endoscopic control in patients with middle ear and mastoid cholesteatoma

#### Protocol summary

##### Study aim

The purpose of this study was to compare residual cholesteatoma in two methods of tympanomastoidectomy CWD and ICW with endoscopic control in patients with middle ear and mastoid cholesteatoma.

##### Design

A concealed, randomized, blinded, sham-controlled clinical trial with a parallel-group design of 40 patients, enrolled between April 2011 and April 2015 and followed for four years.

##### Settings and conduct

In a randomized clinical trial, 40 patients referred to Amir Al Hospital with middle ear cholesteatoma selected for tympanomastoidectomy were enrolled. They then underwent either endoscopic ICW or CWD without the need for chain reconstruction. After surgery, the patients were microscopically examined at 3, 6, 9 and 12 months, in the 12th month, patients with local anesthesia and sedation underwent middle ear revision surgery and, if possible, chain reconstruction. Mid-ear surgery for pearl and residual cholesteatoma was checked using a 30 ° and 2.7 mm endoscope and relapse data was recorded.

##### Participants/Inclusion and exclusion criteria

inclusion criteria : Patients diagnosed with microscopic examination of the cholesteatoma and who were candidates for surgery were enrolled with any degree of hearing. Exclusion criteria: 1) Cholesteatoma associated with posterior wall destruction 2) The patient does not seek follow-up or postoperative follow-up examination for any reason. 3) the patient has complications of cholesteatoma, such as dizziness, facial palsy, moderate to high sensory neuronal hearing loss and above Moderate, intracranial complications, mastoid abscess, lateral sinus thrombosis, etc. 4) Failure after graft surgery 5) The patient should be treated

##### Intervention groups

Comparison of residual cholesteatoma in subjects with middle ear and mastoid cholesteatoma

##### Main outcome variables

The ICW method is comparable to the endoscopic control of the CWD method, with much fewer complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191123045472N1**

Registration date: **2020-07-13, 1399/04/23**

Registration timing: **retrospective**

Last update: **2020-07-13, 1399/04/23**

Update count: **0**

##### Registration date

2020-07-13, 1399/04/23

##### Registrant information

##### Name

Pedram Borghei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 9253

##### Email address

entrc.tums@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2011-04-04, 1390/01/15

##### Expected recruitment end date

2015-04-04, 1394/01/15

**Actual recruitment start date**

2011-04-04, 1390/01/15

**Actual recruitment end date**

2015-04-04, 1394/01/15

**Trial completion date**

2015-04-04, 1394/01/15

**Scientific title**

Comparison of residual cholesteatoma in two methods of tympanomastoidectomy CWD and ICW with endoscopic control in patients with middle ear and mastoid cholesteatoma

**Public title**

Comparison of CWD and ICW tympanomastoidectomy with endoscopic control to evaluate residual cholesteatoma for patients with middle and mastoid cholesteatoma

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who were diagnosed with microscopic examination of cholesteatoma and who were candidates for surgery, with any hearing loss

**Exclusion criteria:**

Patient with cholesteatoma with posterior wall destruction The patient does not follow-up or postoperative follow-up examinations for any reason. The patient has complications of cholesteatoma, such as dizziness, facial paralysis, sensorineural hearing loss average or above average, intracranial complications, mastoid abscess, lateral sinus thrombosis, etc The patient should be treated with revision Failure after graft surgery

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization type is blocked randomization. Foursquare blocks of intervention group(A) and control(B) are defined on cards 1-6 (AABB,ABAB,ABBA,BBAA,BABA,BAAB), the cards are placed inside the envelope. Then the cards are selected randomly and then the random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The study is single-blind. In the informed consent, it is mentioned that the patients will be treated randomly in one of two methods (both are the standard method and the same postoperative appearance), so patients are unaware of which group they are involved in.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods St,Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2006-06-18, 1385/03/28

**Ethics committee reference number**

394758-3531-48-01-85

**Health conditions studied****1****Description of health condition studied**

Tympanomastoidectomy in people with cholesteatoma

**ICD-10 code**

H71

**ICD-10 code description**

Cholesteatoma of middle ear

**Primary outcomes****1****Description**

The amount of remaining cholesteatoma

**Timepoint**

3 months, 6 months, 9 months and 12 months

**Method of measurement**

Endoscope 30 ° and 7.2 mm

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

"Intervention group": Twenty patients with cholesteatoma in the intervention group underwent CWD (tympanomastoidectomy with posterior wall resection) without chain reconstruction. Posterior wall resection (CWD) is a standard surgical treatment for cholesteatoma, but it has many complications. After surgery, patients were examined microscopically at 3, 6, 9, and 12 months, and then at the 12th month, patients with local anesthesia and sedation underwent middle ear surgery and, if possible, chain reconstruction. Midterm surgery was performed to check for pearl and residual cholesteatoma using a 30 ° and 2.7 mm endoscope, and recurrence rate was recorded. Mann-Whitney and Fisher's exact tests were used for data analysis.

#### Category

Treatment - Surgery

### 2

#### Description

"Control group:" In the control group, twenty patients with surgical candidate cholesteatoma underwent endoscopic ICW (tympanomastoidectomy with posterior wall preservation). This procedure has fewer complications, but access to middle ear rosettes is more difficult than CWD. In this study, an endoscope was used to access ear rosettes that are not accessible by microscope. After surgery, patients were examined microscopically at 3, 6, 9, and 12 months, and then at the 12th month, patients with local anesthesia and sedation underwent middle ear surgery and, if possible, chain reconstruction. Midterm surgery was performed to check for pearl and residual cholesteatoma using a 30 ° and 2.7 mm endoscope, and recurrence rate was recorded. Mann-Whitney and Fisher's exact tests were used for data analysis.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

AmirAlam hospital

##### Full name of responsible person

Dr. Pedram Borghei

##### Street address

AmirAlam hospital , North Saadi Ave

##### City

Tehran

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Tehran

##### Postal code

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Ali Sahraeian

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#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Pedram Borghei

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Ear, Nose, and Throat

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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