Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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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Specialist
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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