Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing Scalpel versus Electrocautery Methods for post auricular surgical site incision of tympanoplasty for patients with chronic otitis media

Protocol summary

Study aim

Evaluating the results of two post-auricular incision methods by scalpel or electrocautery to perform tympanoplasty.

Design

This study will be performed as a prospective, double-blind and randomized clinical trial. A total of 100 patients will undergo tympanoplasty by scalpel or electrocautery incision according to the randomization table and will be placed in 2 groups.

Settings and conduct

This study will be performed at the ENT, Head and Neck Surgery department of Taleghani Hospital, Tehran, Iran. Retrauricular skin and subcutaneous incision approach will be performed by electrocautery (group A) or scalpel (group B). Information is recorded and collected before, during or after surgery for all patients. Criteria related to site incision include: site of incision (post-auricular sulcus or along the posterior root line to sulcus), time of incision, wound characteristics (wound length), blood loss rate, incision site infection, ecchymosis, seroma Hematoma, Wound Detachment, Objective Scar Measurement (VSS), and Subjective Scar Score and Visual Analysis Scale (VAS). Patients and data analysts will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with chronic otitis media (COM) indicated for tympanoplasty with retro auricular approach Exclusion criteria: history of complication in other ear surgery

Intervention groups

Tympanoplasty will be performed with a scalpel or electrocautery incision of Retro-auricular skin and subcutaneous incision approach

Main outcome variables

frequency of infection, ecchymosis, hematoma, seroma, wound detachment and bleeding of surgical site incision, postoperative pain using VAS, amount of scar left by surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210210050316N1**
Registration date: **2021-02-24, 1399/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-24, 1399/12/06**
Update count: **0**

Registration date

2021-02-24, 1399/12/06

Registrant information

Name
Sara Sharifi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4417 3663
Email address
sara.sharifi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Scalpel versus Electrocautery Methods for post auricular surgical site incision of tympanoplasty for patients with chronic otitis media

Public title

Comparing of 2 primary surgical incision methods in patients' eardrum repair surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with chronic otitis media candidate for tympanoplasty with retroauricular approach

Exclusion criteria:

Active infection of other ear Retroauricular skin infection History of radiotherapy of head and neck Complications of surgical site incision of other ear collagen vascular disease Immunocompromised patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to 2 groups for tympanoplasty surgery by scalpel or electrocautery cutting, based on table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

1.A complete explanation of the study will be performed for the patients; And patients will be given a full explanation of the advantages and disadvantages of each surgical incision method, and if they consent, one of the studied methods will be done randomly, of which they will not be aware. 2. By numbering each of the groups into groups 1 and 2 in the statistical file, and not informing the person analyzing the information about their content

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical sciences

Street address

no4, 23 alley, south Parvaneh, West Ferdows, District 5

City

Tehran

Province

Tehran

Postal code

1483655418

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.SBMU.MSP.REC.1398.565

Health conditions studied

1

Description of health condition studied

chronic Otitis Media

ICD-10 code

H65.3

ICD-10 code description

Chronic mucoid otitis media

Primary outcomes

1

Description

Complications of surgical site incision

Timepoint

day1 ,7, 30 and month6 after surgery

Method of measurement

Observation and checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: electrocautery retroauricular incision,

Category

Treatment - Surgery

2

Description
Intervention group2: scalpel retroauricular incision
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital, Tehran
Full name of responsible person
Sara Sharifi
Street address
department of ENT and head and Neck surgery, Taleghani hospital, Velenjak Street
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 4417 3663
Email
sarasharifi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences
Street address
Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 4417 3663
Email
sarasharifi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sara Sharifi
Position
Specialist Assistant of Head and neck surgery and ENT
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
Street address
No4, 23th Alley, South Parvaneh Ave, West Ferdows Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
111111111
Phone
+98 21 4417 3663
Fax
Email
saravel1212@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sara Sharifi
Position
Specialist Assistant of Head and neck surgery and ENT
Latest degree
Medical doctor
Other areas of specialty/work
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No4, 23th Alley, South Parvaneh Ave, West Ferdows Blvd, Tehran
City
Tehran
Province
Tehran
Postal code

1483655418

Phone
+98 21 4417 3663

Fax

Email
saravel1212@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Sara Sharifi

Position
Specialist Assistant of Head and neck surgery and ENT

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Province
Tehran

Postal code
1483655418

Phone
+98 21 4417 3663

Fax

Email
saravel1212@yahoo.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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
.

When the data will become available and for how long
.

To whom data/document is available
.

Under which criteria data/document could be used
.

From where data/document is obtainable
.

What processes are involved for a request to access data/document
.

Comments