

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation of the efficacy of endoscopic ear surgery compared to microscopic method on pain severity and graft success rate among patients with chronic otitis media: a randomized clinical trial

Protocol summary

Study aim

This study aims to investigate the clinical benefits and success rates of endoscopy and microscopy surgical approaches of tympanoplasty in patients with chronic otitis media.

Design

A randomized clinical trial with an open-label design with two randomized parallel intervention groups on 34 patients. Simple randomization will be used according to computerized generated numbers using random allocation software.

Settings and conduct

Place of study: This study will be conducted at Urmia Imam Khomeini Hospital in Urmia. Study population: The patients who will be candidates for tympanoplasty surgery due to chronic otitis media. Blinding won't be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients with a mucoid type of chronic suppurative otitis media; the presence of conductive hearing loss with no sensorineural hearing loss; good general physical condition; no evidence of infection in nose, throat, and paranasal sinuses Non-inclusion criteria: smokers; participants with cholesteatoma; participants with otosclerosis; diabetes; individuals with cardiovascular disease and chronic liver or renal diseases

Intervention groups

Intervention group 1: The microscopic group, in which an incision will be executed behind the ear with subsequent entry into the canal. The Lempert method will be served as the basis for the lifting of the tympanomeatal flap. Intervention group 2: The endoscopic group that the incisions for this approach will be made approximately 5 to 6 millimeters lateral (to the side) to the tympanic annulus in the posterior part of the external auditory canal (EAC). By lifting a tympanomeatal flap, the surgeon

will be able to visualize the middle ear cavity.

Main outcome variables

Graft success rate; pain severity; operation duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221002056073N2**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Reza Samarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 7286

Email address

samareireza@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of endoscopic ear surgery compared to microscopic method on pain severity and graft success rate among patients with chronic otitis media: a randomized clinical trial

Public title

The success rate of two surgical approaches of Tympanoplasty

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with a mucoid type of chronic suppurative otitis media Presence of conductive hearing loss with no sensorineural hearing loss in patients Patients with good general physical condition Patients with no evidence of infection in nose Patients with throat and paranasal sinuses undergoing surgery for the first time for the concerned ear

Exclusion criteria:

Individuals younger than 14 years of age and older than 55 years Smokers Participants with contralateral ear disease Patients with cholesteatoma Patients with otosclerosis Patients with tympanosclerotic plaque or granulation tissue in the middle ear Patients undergoing simultaneous mastoid surgery Revision cases and associated poor general condition Those with preoperative medical issues such as asthma Diabetic patients Patients with cardiovascular disease Patients with chronic liver or renal diseases

Age

From **14 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients will be done by simple randomization according to computerized generated numbers using random allocation software that half of the participants will be assigned to the endoscopy group based on odd numbers and the other half will be assigned to the microscopic group based on even numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Urmia University of Medical Sciences

Street address

Imam Khomeini Educational Hospital, Ershad Ave., Ayatollah Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.UMSU.REC.1398.266

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

Chronic Otitis media

ICD-10 code

H65.20

ICD-10 code description

Chronic serous otitis media

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

Graft success rate

Timepoint

The graft success rate will be assessed between 3-6 months postoperatively.

Method of measurement

Endoscopic assessment

2**Description**

Pain severity

Timepoint

Pain severity will be assessed immediately after surgery and one day after surgery.

Method of measurement

Pain severity will be evaluated and recorded by the patient using an 11-point numerical rating scale (NRS-11,

range 0 to 10).

3

Description

Duration of surgery

Timepoint

The duration of the surgery will be measured intraoperatively.

Method of measurement

Using a chronometer (in minute)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the microscopy group (a common approach) the Opmi Vario S88 microscope from Carl Zeiss in Oberkochen, Germany will be used for investigation. In the microscopic approach, an incision will be executed behind the ear with subsequent entry into the canal. The Lempert method will be served as the basis for the lifting of the tympanomeatal flap.

Category

Diagnosis

2

Description

Intervention group 2: The endoscopic group (the new approach) will be employed an endoscopic system manufactured by Karl Storz in Tuttlingen, Germany. Rigid endoscopes with either 0- or 30-degree angles and diameters of 3.0- or 4.0-mm, and lengths of 11 or 16 cm (also from Karl Storz) will be used for the procedure. The incisions for this approach will be made in the posterior part of the EAC approximately 5 to 6 mm lateral to tympanic annulus, perpendicular to the TM tympanic at both the superior and the inferior ends of the first incision.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini University Hospital

Full name of responsible person

Reza Samarei

Street address

Imam Khomeini Educational Hospital, Ershad Ave.,
Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

samareireza@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

Research and Technology Vice-Chancellor Building,
Headquarters of Urmia University of Medical Sciences,
Ourgans St., Resalat Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3193 7224

Email

saber@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Reza Samarei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Khomeini Educational Hospital, Ershad Ave.,
Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

samareireza@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Reza Samarei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Khomeini Educational Hospital, Ershad Ave.,
Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

samareireza@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Reza Samarei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Imam Khomeini Educational Hospital, Ershad Ave.,
Modarres Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

samareireza@gmail.com

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable