

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effects of topical drops on the result of tympanoplasty or tympanomastoidectomy surgery in patients with chronic otitis media at valiasr and Baqiyatallah Hospital in 1392-1393

Protocol summary

Registration timing: **retrospective**

Study aim

To evaluate the effects of topical drops on the result of tympanoplasty or tympanomastoidectomy surgery in patients with chronic otitis media at valiasr and Baqiyatallah Hospital in 1392-1393

Last update: **2020-08-11, 1399/05/21**

Update count: **1**

Registration date

2020-08-10, 1399/05/20

Design

Phase 3, randomized control clinical trial with parallel group that performed on 80 patients. Randomization was done using random number table.

Registrant information

Name

Saman Rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

All patients had surgery by three expert surgeon in Valiasr and Baqiyatallah hospital

Participants/Inclusion and exclusion criteria

Patients with chronic otitis media came to Valiasr and Baqiyatallah hospital who had undertaken tympanoplasty and tympanomastoidectomy at Valiasr hospital. in the case of immune deficiency due to diabetes, HIV, oral corticosteroid use, History of cholesteatoma, Patient rejection and History of previous ear surgery, patients excluded.

Recruitment status

Recruitment complete

Funding source

Intervention groups

in the intervention group, after removal of dressing, patients received ciprofloxacin eye drop 0.3% 3 to 4 times a day and betamethasone eye drop 0.1% 3 to 4 times a day for a week. patients in the control group received no drops.

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2015-03-03, 1393/12/12

Actual recruitment start date

2013-03-21, 1392/01/01

Actual recruitment end date

2015-03-03, 1393/12/12

Trial completion date

2015-03-03, 1393/12/12

Main outcome variables

Otorrhea, graft success, otitis externa, itching.

Scientific title

Effects of topical drops on the result of tympanoplasty or tympanomastoidectomy surgery in patients with chronic otitis media at valiasr and Baqiyatallah Hospital in 1392-1393

General information

Reason for update

To mention supervisor.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048241N1**

Registration date: **2020-08-10, 1399/05/20**

Public title

Effects of topical drops on the result of tympanoplasty or tympanomastoidectomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic otitis media indication for surgery patient preference

Exclusion criteria:

Patients with immune deficiency due to diabetes, HIV, oral corticosteroid use History of cholesteatoma Patient rejection History of previous ear surgery

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a simple randomization method using a table of random numbers used. To use the number of random numbers, we first determine the reading path of the table numbers (for example, top, bottom, left or right). Then we assume certain even numbers for intervention group receiving topical drops and odd numbers for control group. Then we touch on one of the numbers and move in one of the predetermined directions and record the numbers and assign them to different groups.

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

The Ethics Committee of Tehran University of Medical Sciences

Street address

Qods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-06-06, 1394/03/16

Ethics committee reference number

86100023

Health conditions studied

1

Description of health condition studied

Chronic otitis media

ICD-10 code

H66.3

ICD-10 code description

Other chronic suppurative otitis media

Primary outcomes

1

Description

Otorrhea due to graft failure

Timepoint

Week 6 and week 12 after surgery

Method of measurement

Examination by microscope

2

Description

Tympanic membrane graft success

Timepoint

Week 6 and week 12 after surgery

Method of measurement

Examination by microscope

3

Description

Post surgery otitis externa

Timepoint

Week 6 and week 12 after surgery

Method of measurement

Examination by microscope

4

Description

Post surgery itching

Timepoint

Week 6 and week 12 after surgery

Method of measurement

Examination by microscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after removal of dressing, patients received ciprofloxacin eye drop 0.3% 3 to 4 times a day and betamethasone eye drop 0.1% 3 to 4 times a day for a week.

Category

Treatment - Drugs

2

Description

Control group: In patients in this group, no topical drops, prescribes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Saman Rezaeian

Street address

Mulla Sadra Street. Vanak Square

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2

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Saman Rezaeian

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Dr Gharib St. Keshavarz Blv.

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lmamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

MS Research Center, Sina Hospital, Hasan Abad Square- Emam Khomeyni Street

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sahraian1350@yahoo.com

Grant name

Grant code / Reference number

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

Yes

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

Saman Rezaeian

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahtab Rabbani Anari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Saman Rezaeian

Position

Otology fellowship

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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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

Not applicable

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