

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Prevalence of early post-ventilation tube otorrhea

Protocol summary

Summary

Objective of this study is to compare the post-tympanostomy otorrhea in three treatment groups (irrigation of middle ear with isotonic saline, oral amoxicillin, and ciprofloxacin drop) with controls. In a single blind prospective stage III randomized clinical trial multicentre (Dastghaib and Khalili hospitals of Shiraz and Hamedan Besat hospital), Five hundred thirty ears in who had tympanostomy tube (TT), insertion because of OME between April 2006 and March 2013 were included. An inclusion criterion was age, less than 15 years. Also Candidacy for surgery was based on the guide line of American Academy Of Otolaryngology -Head & Neck Surgery. Exclusion criteria were: chronic sinusitis, cleft palate, craniofacial abnormalities, known SNHL, complication of otitis media, and age more than 15. Patients were randomized into 4 groups regarding the type of preventive therapy: In group isotonic saline the middle ear cavity was irrigated with isotonic saline. In group oral amoxicillin the patient received (oral amoxicillin) for 7 days. In antibiotic drop group the patient received ciprofloxacin drop for 3 days. Finally, the control group received no treatment. Our primary outcome was post-tympanostomy otorrhea which evaluated by an assessor physician by microscopic otoscopy within first 2 weeks (3 days, one week and two weeks) after operation. During operation the middle ear status documented in five groups: normal, congested mucosa, or secretory (mucoid, serous, or pussy) as secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112315496N1**
Registration date: **2014-01-13, 1392/10/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-13, 1392/10/23

Registrant information

Name

Sareh Roosta

Name of organization / entity

Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2006-03-21, 1385/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevalence of early post-ventilation tube otorrhea

Public title

Prevalence of early post-Ventilation tube otorrhea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: any child undergoing TT placement for

COME with and without undergoing concurrent adenoidectomy based on the guide line of American Academy of Otolaryngology-Head & Neck Surgery (AAO-HNS) on diagnosis and management of OME(May 2004) that included children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms. Exclusion criteria: allergy to penicillin; chronic sinusitis; children who had previously undergone myringotomy and/or tube insertion; cleft palate; sensory neural hearing loss; complications of otitis media; craniofacial dysmorphism; mucociliary clearance disorders; immunodeficiency and age more than 15 years old.

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **530**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2006-03-19, 1384/12/28

Ethics committee reference number

84-2745

Health conditions studied

1

Description of health condition studied

post-tympanostomy otorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-tympanostomy otorrhea

Timepoint

3 day, one week, 2 weeks after operation

Method of measurement

Microscopic otoscopy

Secondary outcomes

1

Description

The middle ear status: normal, congested mucosa, or secretory(muroid, serous, or pussy).

Timepoint

Intra-operative

Method of measurement

Microscopic otoscopy

Intervention groups

1

Description

In the second intervention group, the patients receive oral antibiotic (amoxicillin, 50 mg/kg), three times a day for 7 days after operation.

Category

Treatment - Drugs

2

Description

In the first intervention group, the middle ear cavity of the patient is irrigates with isotonic saline until the sticky fluid cleared.

Category

Treatment - Other

3

Description

In the third intervention group, the patient recieves topical ciprofloxacin drop (ciplex, Sinadarou company), 4 drops three times a day, for 3 days after operation.

Category

Treatment - Drugs

4

Description

The control group, receives no treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili hospital

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Dastgheib hospital

Full name of responsible person

Street address

City

Shiraz

3

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Street address

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Otolaryngology, Shiraz University of medical sciences

Full name of responsible person

Mohammad Faramarzi

Position

Associate professor of otolaryngology

Other areas of specialty/work

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Center for Development of Clinical Studies of Nemazee hospital- Vice Chancellery of Research and Tec

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty