Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Compare the efficacy of ciprofloxacin drop with a drop of levofloxacin in patients with chronic supprative otitis media (csom) clients to Zahedan Khatam-al-anbia hospital during 2016-2018

Protocol summary

Study aim

Comparing the efficacy of ciprofloxacin drop with a drop of levofloxacin in pateints with chronic suppurative otitis media clients Khatam hospital, Zahedan, Iran during 2017-2019

Design

In this study, 160 patients were randomly divided into groups of less than 20 years of age, 20 to 40 years, and 40 to 60 consecutive weeks, treated with ciprofloxacin and drops of levofloxacin. Groups are matched according to age and gender.

Settings and conduct

This study was conducted as an interventional intervention-clinical trial in ENT of Khatam-ol-Anbia Hospital in Zahedan for all patients with chronic otitis media with atherosclerosis for at least 12 weeks admitted to Khatam-ol-Anbia Hospital in Zahedan, Iran. Years 2016-2018, which are diagnosed with the history and clinical findings and are treated by an ENT doctor. In this study, patients were randomly assigned into two treatment groups, the first group received ciprofloxacin-betamethasone and the second group of levofloxacin-betamethasone drop. Two weeks after treatment, all patients are evaluated to evaluate the response to treatment.

Participants/Inclusion and exclusion criteria

Entrance conditions include patients with chronic suppurative otitis media.

Intervention groups

The intervention group included recipients betamethasone drop (0.1%) (4 times daily for 2 minutes) and after discharge of ciprofloxacin drop 4% (every 6 hours 4 drops for 2-3 minutes) The intervention group included recipients betamethasone drop (0.1%) and then levofloxacin 0.5% drop, as in the above procedure People who participated in the study after cleaning the ear canal by suction and performing an audiometry before and after treatment to assess hearing, Every day, the entire ear canal is filled up with drops 4 times a day and completely discharged after 2 minutes

Main outcome variables

Treatment of chronic suppurative otitis media

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170731035409N2**
Registration date: **2018-05-05, 1397/02/15**
Registration timing: **retrospective**

Last update: **2018-05-05, 1397/02/15**
Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 0669

Email address

mostafa.nakhaei@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the efficacy of ciprofloxacin drop with a drop of levofloxacin in patients with chronic supprative otitis media (csom) clients to Zahedan Khatam-al-anbia hospital during 2016-2018

Public title

Compare the efficacy of ciprofloxacin drop with a drop of levofloxacin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not use cigarette drugs Not pregnancy Lack of hospitalization in the last three weeks No history of other ear diseases and ear surgery The recent lack of topical or systemic antibiotics (last three weeks) Absence of viral infections in the last three weeks Insensitivity to the fluoroquinolone group Lack of simultaneous use of systemic drugs with auto-toxic effects Non-fungal infection of the outer and middle ear simultaneously Do not use concomitant immunosuppressive drugs

Exclusion criteria:

Patients who did not complete the prescribed treatment for any reason during the study Use of other medicines for treatment Exposed to ototoxic materials

Age

To **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is such that after the arrival of patients, patients are classified into two groups according to gender and age matched

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

Zahedan University Ethics Committee

Street address

No. 47, Alborz Ave., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817987741

Approval date

2017-04-16, 1396/01/27

Ethics committee reference number

IR.ZAUMS.REC.1396. 11

Health conditions studied

1

Description of health condition studied

Chronic Suppurative Otitis media

ICD-10 code

H66.3

ICD-10 code description

Chronic suppurative otitis media NOS

Primary outcomes

1

Description

Recovery situation

Timepoint

2 weeks after the first visit

Method of measurement

The symptoms of the illness that the patient is referring to include pain, discharge, and hearing loss are resolved.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving betamethasone drop 0.1% (4 times daily for 2 minutes) and after discharge of ciprofloxacin 0.4% (every 6 hours 4 drops for 2-3 min) for 2 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Patients receiving betamethasone drop 0.1% (4 times daily for 2 minutes) and after discharge of Levofloxacin 0.5% (every 6 hours 4 drops for 2-3 min) for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-Ol-Anbia Hospital

Full name of responsible person

Dr Reza Ghariby

Street address

Khatam-Ol-Anbia Hospital, Jam e Jam Avenue, Zahedan

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khatamhospital_zah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Hushang Rafighdust

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

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public@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr Reza Ghariby

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
proposal
When the data will become available and for how long
2018
To whom data/document is available
public
Under which criteria data/document could be used
In order to do research
From where data/document is obtainable
Zahedan University of Medical Sciences website
What processes are involved for a request to access data/document
By accessing the relevant sites, you can access the materials.
Comments