

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of therapeutic effect of ciprofloxacin powder and drops in the chronic bacterial otitis media

Protocol summary

Study aim

The aim of this study is to compare therapeutic effect of ciprofloxacin powder with ciprofloxacin drop in chronic bacterial otitis media

Design

Clinical trial with control group, randomized, total positive samples in 2 groups: 80 persons, beginning on October 2018

Settings and conduct

Patients with ear problems referred to ENT department of Ayatollah Rouhani Hospital in Babol, Iran. At the clinic, patients are examined by a specialist in otolaryngology. A questionnaire including demographic and disease information is filled out for all patients who have inclusion criteria. Two samples of pus and ear discharge will be taken by the specialist (one for direct examination and the other for culture). After suction, the patient will be randomly assigned to one of the intervention or control groups. They are treated according to the assigned group. Samples will be sent to the mycology and microbiology laboratories in Babol University of Medical Sciences. Laboratory colleagues without being aware of grouping will perform the necessary tests to confirm the organism causing the disease and then obtained data will be analyzed.

Participants/Inclusion and exclusion criteria

All patients with chronic bacterial otitis media will enter the study. Patients with suspected mixed infection as well as patients with external otitis infection will exclude in the study

Intervention groups

Intervention group: After suction, 30 mg ciprofloxacin powder (Ronak pharmaceutical company, Kaveh industrial town, Iran) will use for once, by insufflation in to middle ear space and the existing perforation accompanying the microscopic guide. Control group: After suctioning of the ear canal, 3 drops of ciprofloxacin 0.3% (Sina Darou Pharmaceutical Company, Tehran, Iran) are poured once into the ear canal. All patients will

be visited after two weeks.

Main outcome variables

Pain; swelling; discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130427013136N7**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Saeid Mahdavi Omran

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of ciprofloxacin powder and drops in the chronic bacterial otitis media

Public title

The effects of ciprofloxacin on the treatment of bacterial otitis media

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with chronic bacterial otitis media

Exclusion criteria:

Suspected Patients to mixed bacterial and fungal otitis
Suspected Patients to otomycosis patients with external
otitis patients without rupture of the eardrum

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

According to inclusion and exclusion criteria, patients who referred to the physician will fall into two groups, consecutively. So that the first eligible patients will be entered in group 1 and the next one in group 2. Sampling will be continued till the desired number.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the primary specialist is informed about the type of drug, due to the apparent difference between the packaging and its application of them, but another otolaryngologist will be evaluate the patients at the follow-up stage. Therefore, the judgment about the effectiveness of these drugs will be based only on the clinical findings of the disease at this stage, by the second specialist. Laboratory experts who make the final diagnosis according to direct examination and culture on media results, also will perform the necessary tests according to a patient code; and they are not aware of the patient group. All patients also aware of the type of treatment, depending on the form and how the drug is used.

Placebo

Not used

Assignment

Parallel

Other design features

Ciprofloxacin powder is not available in Iran's drug store, thus the tablet form of this drug is converted into powder by a pharmacologist.

Secondary Ids

empty

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

Ethics committee of Babol University of Medical Sciences

Street address

School of Medicine, Babol University of Medical Sciences, University Square, Ganj afrouz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

MUBABOL.HRI.REC.1396.202

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

Chronic bacterial otitis media

ICD-10 code

H65.3

ICD-10 code description

Chronic mucoid otitis media

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

Pain

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Severity of pain will determined by the patient's expression or pain index (Visual Analog Scale-VAS) which are between 0-10.

2**Description**

Swelling

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Severity of swelling will determine based on the

examination of the ear by the physician.

3

Description

Discharge

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Severity of discharge will determine based on the examination of the ear by the physician.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After suction, 30 mg ciprofloxacin powder (Ronak pharmaceutical company, Kaveh industrial town, Iran) will use for once, by insufflation in to middle ear space and the existing perforation accompanying the microscopic guide.

Category

Treatment - Drugs

2

Description

Control group: After suctioning of the ear canal, 3 drops of ciprofloxacin 0.3% (Sina Darou Pharmaceutical Company, Tehran, Iran) are poured once into the ear canal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ENT clinic, Aytollah Rouhani Hospital

Full name of responsible person

Dr Keyvan Kiakojuri

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ENT Clinic, Aytollah Rouhani Hospital, Ganj Afrooz st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Saeid Mahdavi Omran

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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