Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 refereed 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

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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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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
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Full name of responsible person
Saeid Mahdavi Omran
Position
Associate Professor
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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