

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ciprofloxacin powder accompanying with topical betamethasone compare to ciprofloxacin drop accompanying with betamethasone drope in the treatment of bacterial external otitis

Protocol summary

Study aim

Comparison of two methods of treatment, ciprofloxacin powder with betamethasone ointment compare to ciprofloxacin drops with betamethasone drop in the treatment of bacterial infection of the external ear after suction clearness.

Design

120 patients with external ear infections who are eligible for inclusion in the study are selected. Participants are randomly divided into intervention and control groups (the same as the usual medicine).

Settings and conduct

Patients who referred to the ENT clinic of Rouhani Hospital of Babol, were randomly divided into two groups of 60 persons (which can be identified with a 95% confidence interval and 80% test power of 0.5 unit difference between the groups statistically.), In group one, after suction clearance, ciprofloxacin powder with betamethasone ointment will be used and , after suction clearance, ciprofloxacin drops with betamethasone drop in the ear canal of second group were used.

Participants/Inclusion and exclusion criteria

The presence of infection in the external ear and the patient's desire to appear in the study as a inclusion, and ear tympanic rupture, mixed infection and reluctance to attend are as exclusion criteria.

Intervention groups

Cotrol group: Ciprofloxacin drop with betamethasone drop
Case group: Ciprofloxacin powder with betamethasone ointment

Main outcome variables

Pain, Swelling, Secretion and Itching.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130427013136N5**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name

Saeid Mahdavi Omran

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1219 9936

Email address

s.mahdavi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ciprofloxacin powder accompanying with

topical betamethasone compare to ciprofloxacin drop accompanying with betamethasone drope in the treatment of bacterial external otitis

Public title
The effect of ciprofloxacin and betamethasone in the treatment of otitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients suspected of external bacterial infection
Exclusion criteria:
Patients with the rupture of the tympanic membrane
Patients with mixed infection

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Each person is randomly assigned to one of two groups using a random number table. The status of each person is related to secretary of the department.

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the initial code for each patients, the physician and the laboratory staff are not aware from of each group.

Placebo
Not used

Assignment
Parallel

Other design features
According to the presence of Ciprofloxacin tablet (FDA approved) in the drugstore, this drug is converted to powder by the pharmacologist for use on the patient. Due to the local application of the drug, there will be no side effects on the patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ettics committee of Babol University of Medical Sciences

Street address

Ganj Afrooz Ave

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

MUBABOL.HRI.REC.1396.201

Health conditions studied

1

Description of health condition studied

Bacterial of otitis externa

ICD-10 code

H62.0

ICD-10 code description

Otitis externa in bacterial diseases classified elsewhere

Primary outcomes

1

Description

The change degree of ear itching

Timepoint

Evaluation of the therapeutic effect of the two drugs occurs after 2 weeks.

Method of measurement

The question of the patient about the itching can be helpful.

2

Description

The pain in the ears (VAS)

Timepoint

Evaluation of the therapeutic effect of the two drugs occurs after 2 weeks.

Method of measurement

We will use from A 10-point VAS to measure pain.

3

Description

Change the secretion rate of swelling

Timepoint

Evaluation of the therapeutic effect of the two drugs occurs after 2 weeks.

Method of measurement

These variables are evaluated based on the physician's observations of the ear.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ciprofloxacin powder accompanying with topical betamethasone will be use in the outer ear space, using insuflation and soap, respectively.

Category

Treatment - Drugs

2

Description

Control group: Ciprofloxacin drop and betamethasone drop will be use in the outer ear space.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani, Babol

Full name of responsible person

Dr. Keyvan Kiakojouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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rezaghadimi@yahoo.com

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

Dr. Saeid Mahdavi Omran

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Keyvan Kiakojouri

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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 more 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