

# 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

#### Street address

Ganj Afrooz

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#### Phone

+98 11 3219 9936

#### Email

kia\_ko13358@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Dr. Reza Ghadimi

#### Street address

Ganj Afrooz

#### City

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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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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**  
Microbiology  
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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