

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Feb 2026

### Comparison of the efficacy of ceftazidime powder and Ciprosonate drop on treatment of external bacterial otitis

#### Protocol summary

##### Study aim

Compare therapeutic effect of Ceftazidime powder with ciprosonate drop in bacterial otitis externa

##### Design

Clinical trial with control group, randomized, total positive samples in 2 groups: 140 persons, beginning on April 2020

##### 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

Inclusion criteria: All patients with bacterial otitis externa. Exclusion criteria: Patients with suspected fungal or mixed infection as well as patients with otitis media

##### Intervention groups

Intervention group: After suction, 30 mg Ceftazidime powder (Exir pharmaceutical Company, Burojerd, Iran) will use for once, by insufflation in to middle ear space and the existing perforation accompanying the microscopic guide. Control group: After suction, ciprosonate drop 0.3% (Sina Darou Pharmaceutical Company, Tehran, Iran) will use in the ear canal space for once. All patients will be visited after two weeks.

##### Main outcome variables

Pain; swelling; pus

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130427013136N6**

Registration date: **2020-02-13, 1398/11/24**

Registration timing: **prospective**

Last update: **2020-02-13, 1398/11/24**

Update count: **0**

##### Registration date

2020-02-13, 1398/11/24

##### 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

2020-04-03, 1399/01/15

##### Expected recruitment end date

2021-09-23, 1400/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of ceftazidime powder and Ciprosonate drop on treatment of external bacterial otitis

**Public title**

The efficacy of ceftazidime on bacterial otitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with bacterial otitis externa.

**Exclusion criteria:**

Patients who have fungal infections. Patients who have tympanic membranous perforation Patients with a history of ear surgery. Patients with defective ear canal.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to inclusion and exclusion criteria, Sampling will be done by systematic random sampling way, such that patients who referred to the physician will fall into two groups, consecutively. So that the first eligible patients will be entered in group 1(Intervention) and the next one in group 2 (Control). Sampling will be continued till the desired number.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, except the secretary and laboratory colleagues, they are not aware of the placement of patients in either of these groups, the physician and patient are aware of the type of drug used.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****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**

2020-03-02, 1398/12/12

**Ethics committee reference number**

با توجه به اینکه طرح در دست بررسی در دانشکده می باشد، بنابراین تاریخ ثبت شده احتمالی است و به محض دریافت شماره و تاریخ آن اعلام خواهد شد.

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

Bacterial otitis externa

**ICD-10 code**

H60.90

**ICD-10 code description**

Unspecified otitis externa, unspecified ear

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

Pain

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

En 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**

Secretion

**Timepoint**

Before intervention and 2 weeks after intervention

**Method of measurement**

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

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: En Intervention group: : After suction, 30 mg ciprofloxacin powder (Exir pharmaceutical company, Borujerd, 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: En Control group: After suction, ciprosonate drop 0.3% (Sina Darou Pharmaceutical company, Tehran, Iran) will use in the ear canal space for once.

#### 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

##### Street address

ENT Clinic, Aytollah Rouhani Hospital, Ganj Afroz st.

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+98 11 3223 8301

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info@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr. Reza Ghadimi

##### Street address

Babol University of Medical Sciences, Ganj afroz

Street

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##### Province

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##### Phone

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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

Saeid Mahdavi Omran

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Mycology

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Keyvan Kiakojouri

**Position**

Scientific Board (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**

Scientific Board (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