

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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)

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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 Afrooz st.

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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

Street address

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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

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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