

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of Response to Treatment of Bacterial Acute Otitis Externa Using Topical Ciprofloxacin Alone and Topical Ciprofloxacin Combined with the Initial Application of Betadine Impregnated Mesh

#### Protocol summary

##### Study aim

Comparison of Response to Treatment of Bacterial Acute Otitis Externa Using Topical Ciprofloxacin Alone and Topical Ciprofloxacin Combined with the Initial Application of Betadine Impregnated Mesh

##### Design

Clinical trial with Control Group, with Parallel Groups, Single Blind, Non-Randomized. Patients randomly selected by Physician Divided into Case and control groups and There are 50 People in each Group.

##### Settings and conduct

After referring Patients to the Physician Personal Clinic in Birjand City, First, the Diagnostic Measures are Taken for Them and if See Symptoms of Acute Otitis Externa They will be Included in the Study. The Patients were then randomly selected by Physician divided Into Two Control Groups: Topical Ciprofloxacin (TC) Drop alone and Case: TC Drop were combined with the Initial Application of Betadine Impregnated Mesh .

##### Participants/Inclusion and exclusion criteria

All Patients Over the Age of 10 Years Based on a Physician's Initial Clinical Diagnosis of Bacterial Acute Otitis Externa and Lack of Concomitant Diabetes Immunodeficiency, Pregnancy History of Trauma to the Ear, or Ear Surgery.

##### Intervention groups

In Control Group after dropping Topical Ciprofloxacin (TC) Drop in the Ear and Suctioning for Patients only TC drop Prescribed and They are told that until the First Visit on the Third Day Every 4 hours 4 Drops dropp Inside the Ear Involved. In the Case group after washing with Betadin and suctioning, In addition to TC Drop in Patients' Ear, a Mesh coated whit Betadin is plased and They are told to remove the Mesh 12 hours later and then until the first visit on the Third Day Every 4 hours 4 Drops dropp Inside the Ear Involved.

##### Main outcome variables

Comparison of Response to Treatment of Bacterial Acute Otitis Externa Using Topical Ciprofloxacin Alone and Topical Ciprofloxacin Combined with the Initial Application of Betadine Impregnated Mesh

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190913044761N1**

Registration date: **2019-11-01, 1398/08/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-01, 1398/08/10**

Update count: **0**

##### Registration date

2019-11-01, 1398/08/10

##### Registrant information

##### Name

Mohsen Izadmehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5523 0737

##### Email address

mohsenizadmehr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-27, 1398/02/07

##### Expected recruitment end date

2020-04-26, 1399/02/07

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of Response to Treatment of Bacterial Acute Otitis Externa Using Topical Ciprofloxacin Alone and Topical Ciprofloxacin Combined with the Initial Application of Betadine Impregnated Mesh

**Public title**  
The Effect of Topical Ciprofloxacin Combined with the Initial Application of Betadine Impregnated Mesh in the Treatment of Bacterial Acute Otitis Externa

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All Patients Over the Age of 10 Years Based on a Physician's Initial Clinical Diagnosis of Bacterial Acute Otitis Externa and Lack of Concomitant Diabetes, Immunodeficiency, Pregnancy History of Trauma to the Ear, or Ear Surgery.

**Exclusion criteria:**

Diabetes Immunodeficiency Pregnancy History of Trauma to the Ear Ear Surgery

**Age**  
From **10 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

The Participants in this clinical trial were randomly divided into two groups of Case and Control. Depending on their group, They will receive the appropriate treatment including Topical Ciprofloxacin alone in the Control group and Topical Ciprofloxacin Drop were combined with the Initial Application of Betadine Impregnated Mesh in the Case group. The principal Investigators, who include Specialist Physicians and General Medical Students, Randomly divide the Patients into Two Case and Control groups. Health Personnel Responsible for determining the Microbial Mass of the Patient's Ear are not aware of the Status of segmentation. The Data Collection and Outcome Assessors, Including Specialist Physicians and General medical students, Are aware of the Status of Patient segmentation But the Committee on Safety and Data Monitoring is not aware of the Status of Patient

segmentation.  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Birjand University of Medical Sciences

**Street address**

Doorplate 73, Hafez 6/1, Hafez Street, Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9491879613

**Approval date**

2019-02-25, 1397/12/06

**Ethics committee reference number**

IR.bums.REC.1397.364

**Health conditions studied**

1

**Description of health condition studied**

Bacterial Acute Otitis Externa

**ICD-10 code**

H60.399

**ICD-10 code description**

Other infective otitis externa, unspecified ear

**Primary outcomes**

1

**Description**

Percentage of People with Bacterial Acute Otitis Externa

**Timepoint**

Investigation of catch of Bacterial Acute Otitis Externa at the beginning of the study and 3, 7 and 10 days after Prescription Topical Ciprofloxacin combined with the Initial Application of Betadine Impregnated Mesh

**Method of measurement**

Clinical diagnosis of Specialist Physician

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: In the Case group after washing with Betadin and suctioning, In addition to TC Drop in Patients' Ear, a Mesh coated whit Betadin is plased and They are told to remove the Mesh 12 hours later and then until the first visit on the Third Day Every 4 hours 4 Drops dropp Inside the Ear Involved.

### Category

Treatment - Drugs

2

### Description

Control group: In Control Group after dropping Topical Ciprofloxacin (TC) Drop in the Ear and Suctioning for Patients only Topical Ciprofloxacin drop Prescribed and They are told that until the First Visit on the Third Day Every 4 hours 4 Drops dropp Inside the Ear Involved.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Personal clinic ENT Dr. Mohammad Reza Mofatteh

#### Full name of responsible person

Mohsen Izadmehr

#### Street address

. Doorplate 73, Hafez 6/1, Hafez Street, Moallem Blvd

#### City

Birjand

#### Province

South Khorasan

#### Postal code

9491879613

#### Phone

+98 51 5523 0737

#### Email

mohsenizadmehr@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Toba kazemi

#### Street address

Doorplate 73, Hafez 6/1, Hafez Street, Moallem Blvd

#### City

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#### Phone

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#### Email

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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

Birjand 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

Birjand University of Medical Sciences

#### Full name of responsible person

Mohsen Izadmehr

#### Position

Medical Student

#### Latest degree

A Level or less

#### Other areas of specialty/work

Ear, Nose, and Throat

#### Street address

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Mohammad Reza Mofatteh

#### Position

Assistant Professor

#### Latest degree

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohsen Izadmehr

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available