

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of the Efficacy of Oral Ciprofloxacin with Intravenous Cefazolin and Gentamicin for Acute Endophthalmitis Prophylaxis in Patient Referring to Alzahra Ophthalmologic Hospital in 2014

#### Protocol summary

##### Summary

(1) Objective : To compare the efficacy of oral ciprofloxacin with intravenous cefazolin and gentamicin in acute endophthalmitis prophylaxis (2) Design : Non-randomized , not-blinded , not-placebo-controlled , single-center , phase II - III trial (3) Setting and conduct : Participants : All referred patients to Alzahra Eye Hospital in 2014 to 2015 requiring acute endophthalmitis prophylaxis Inclusion criteria : The need for acute endophthalmitis prophylaxis ; living in Zahedan Exclusion criteria : All patients who have had eye surgery and other eye diseases ; single-eye patients ; patients who are undergoing medical treatment ; less than 18 years of age ; suspicion for fungal infection ; severe infection Sample size : 60 patients (4) Intervention : The eligible patients will be assigned into two thirty patient groups . For group of patients admitted in the service of conductors tablet of ciprofloxacin 500 milligrams twice a day for five days and for patients admitted in the service of other colleagues at Alzahra Eye Hospital intravenous gentamicin 3 mg/kg three times a day and cefazolin 50 mg/kg four times a day for 72 hours will be administered . Patients will be followed for 1 week . (5) Main outcome measure : incidence of acute endophthalmitis

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060818004N1**  
Registration date: **2014-07-13, 1393/04/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-13, 1393/04/22

#### Registrant information

##### Name

Mohammad Hossein Validad

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 1342 5715

##### Email address

validad@zaums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

#### Expected recruitment start date

2014-06-22, 1393/04/01

#### Expected recruitment end date

2015-03-21, 1394/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the Efficacy of Oral Ciprofloxacin with Intravenous Cefazolin and Gentamicin for Acute Endophthalmitis Prophylaxis in Patient Referring to Alzahra Ophthalmologic Hospital in 2014

#### Public title

Efficacy of Oral Ciprofloxacin in acute endophthalmitis prophylaxis

#### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria : The need for acute endophthalmitis prophylaxis ; living in Zahedan  
Exclusion criteria : All patients who have had eye surgery and other eye diseases ; single-eye patients ; patients who are undergoing medical treatment ; less than 18 years of age ; suspicion for fungal infection ; severe infection

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics in Medical Research Committee of Zahedan  
University of Medica Sciences

##### Street address

Dr Hesabi Square , Zahedan University of Medical  
Sciences Complex

##### City

Zahedan

##### Postal code

9816743463

#### Approval date

2014-04-13, 1393/01/24

#### Ethics committee reference number

5801

## Health conditions studied

### 1

#### Description of health condition studied

Purulent Endophthalmitis

#### ICD-10 code

H44

## ICD-10 code description

Panophthalmitis Vitreous abscess

### 2

#### Description of health condition studied

Open globe injury

#### ICD-10 code

S05.4

#### ICD-10 code description

Penetrating wound of orbit with or without foreign body

## Primary outcomes

### 1

#### Description

acute endophthalmitis onset

#### Timepoint

one week

#### Method of measurement

examination

## Secondary outcomes

### 1

#### Description

oral ciprofloxacin adverse effects

#### Timepoint

1 week

#### Method of measurement

history and examination

### 2

#### Description

IV cefazolin and gentamicin adverse effects

#### Timepoint

1 week

#### Method of measurement

history , examination and lab test

## Intervention groups

### 1

#### Description

intervention group : oral Tablet of ciprofloxacin 500 mg  
twice a day for five days

#### Category

Treatment - Drugs

### 2

#### Description

control group : Intravenous cefazolin 50 mg/kg four times  
a day and Intravenous gentamicin 80 mg/kg three times  
a day for 3 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra Eye Hospital

**Full name of responsible person**

Mohammad Hossein Validad

**Street address**

Alzahra Eye Hospital , Before Khatam Square , Shahid Motahari Blvd

**City**

Zahedan

Alzahra Eye Hospital , Before Khatam Square , Shahid Motahari Blvd

**City**

Zahedan

**Postal code**

9816737789

**Phone**

+98 54 1322 4991

**Fax**

+98 54 1323 3550

**Email**

mhovalidad@yahoo.com

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research , Zahedan University of Medical Sciences

**Full name of responsible person**

Mohsen Taheri

**Street address**

Dr Hesabi Square , Zahedan University of Medical Sciences Complex

**City**

Zahedan

**Grant name****Grant code / Reference number**

5801

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research , Zahedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Validad

**Position**

Ophthalmologist

**Other areas of specialty/work****Street address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammad Hossein Validad

**Position**

Ophthalmologist

**Other areas of specialty/work****Street address**

Alzahra Eye Hospital , Before Khatam Square , Shahid Motahari Blvd

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

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**Position**

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## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*