

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison efficacy and safety of topical caspofungin .5% and topical voriconazole 1% in fungal keratitis

#### Protocol summary

##### Study aim

The comparison efficacy and safety of topical caspofungin .5% and topical voriconazole 1% in fungal keratitis

##### Design

Two-arm parallel-group randomized trial with blinded patients, randomized group, phase on 20 patients, use randomization table.

##### Settings and conduct

Patients with unilateral fungal keratitis who have the study's inclusion criteria and do not have any exclusion criteria are enrolled in the study at Farabi Eye Hospital.

##### Participants/Inclusion and exclusion criteria

1) Fungal keratitis that is confirmed either through a positive sample for corneal smear or culture or through diagnosis by confocal scan. 2) A corneal ulcer with a maximum diameter of 5mm, which involves 4mm of the center of the cornea and extends less than 50% of the stromal depth.

##### Intervention groups

Patients diagnosed with fungal keratitis will undergo treatment with two different anti-fungal eye drops. In the first group, patients will receive topical voriconazole 1%. The clinical response, effectiveness, and any systemic or localized drop complications will be evaluated. In the second group, patients will receive topical caspofungin 0.5%. The clinical response, effectiveness, and any systemic or localized complications will also be evaluated.

##### Main outcome variables

Treating fungal corneal ulcers, improving visual acuity, decreasing ocular injection and pain, and controlling corneal infiltration.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231219060471N1**

Registration date: **2024-02-16, 1402/11/27**

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

Last update: **2024-02-16, 1402/11/27**

Update count: **0**

##### Registration date

2024-02-16, 1402/11/27

##### Registrant information

###### Name

mehran zarei ghanavati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5542 4261

###### Email address

m-zareigh@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-19, 1402/10/29

##### Expected recruitment end date

2024-07-09, 1403/04/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison efficacy and safety of topical caspofungin .5% and topical voriconazole 1% in fungal keratitis

##### Public title

The comparison efficacy and safety of topical caspofungin 0.5% and topical voriconazole 1% in fungal keratitis

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Smear or culture positive fungal keratitis or fungal keratitis with negative smear or culture which is diagnosed by confocal scan Corneal ulcer with a 5mm maximum diameter, involving 4 mm of the center of the cornea, and extending less than 50% of the corneal stromal depth

##### **Exclusion criteria:**

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

- Participant
- Data analyser
- Data and Safety Monitoring Board

#### **Sample size**

Target sample size: **20**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

This study uses both block and individual randomization methods, based on random number tables. The samples are divided into two groups (A and B), with 10 randomly selected samples in each group, based on the randomization tables. Additionally, all sequences are randomized.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

The patients participating in this study will be treated by an expert ophthalmologist who will not interfere with their selection process. Patients will be selected randomly based on a randomization table. The main author responsible for evaluating the data will keep blind. Additionally, a data safety and monitoring committee will analyze the study while being blind to the patient's information. All patients will be informed of the study but will not know which medication they are receiving and will remain blind.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

##### **Street address**

Farabi Eye Hospital, Square Qazvin, South Karegar street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1336616351

#### **Approval date**

2023-12-04, 1402/09/13

#### **Ethics committee reference number**

IR.TUMS.FARABIH.REC.1402.027

### **Health conditions studied**

### **1**

#### **Description of health condition studied**

FUNGAL KERATITIS

#### **ICD-10 code**

B35-B49,H1

#### **ICD-10 code description**

Mycoses, Disorders of sclera, cornea, iris and ciliary body, Disorders of sclera and cornea in diseases classified elsewhere

### **Primary outcomes**

### **1**

#### **Description**

The efficacy and safety of topical caspofungin 0.5% and topical voriconazole 1% will be compared in treating fungal keratitis. Clinical response, scar formation, corneal scar size, visual acuity outcomes, and size and depths of corneal infiltration will also be evaluated.

#### **Timepoint**

An ophthalmic examination will be conducted daily during hospitalization, on the 7th, 14th, and 30th days, as well as on the 3rd month.

#### **Method of measurement**

A clinical examination will be conducted by an expert ophthalmologist. The examination will involve the use of a slit-lamp biomicroscopy to detect clinical response and measure the size and depth of infiltration using a caliper. The size and depth of the corneal scar will also be detected with a slit lamp and measured using a caliper. All clinical responses will be recorded by slit-lamp photography in each examination.

### **Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: For the treatment of fungal keratitis, topical caspofungin 0.5% will be administered. A vial of caspofungin 50 mg is to be diluted with 10.5 cc of Ringer Lactate, and the drops should be instilled every hour for 48 hours. The frequency of administration can then be tapered based on the patient's clinical response. Patients will need to visit the clinic on days 7, 14, and 30 then 3rd month for follow-up appointments.

#### Category

Treatment - Drugs

### 2

#### Description

A control group of patients with fungal keratitis will be treated with topical voriconazole 1%. The voriconazole will be diluted with 20 cc of Ringer lactate. Each patient will receive a drop every hour for 48 hours, after which the dosage will be tapered based on clinical response. Patients will be required to visit the clinic on days 7, 14, 30, and 30 months after the treatment for evaluation of clinical response and to monitor for any clinical and systemic side effects.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farabi Eye Hospital

##### Full name of responsible person

Mehran Zarei Ghanavati

##### Street address

Farabi Eye Hospital, Qazvin Square, South Karegar street

##### City

Tehran

##### Province

Tehran

##### Postal code

1336616351

##### Phone

+98 21 5542 1080

##### Email

m-zareigh@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mehran Zarei Ghanavati

##### Street address

Farabi Eye Hospital, Qazvin Square, South Karegar street

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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

Tehran 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

### 2

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohamad taher Rajabi

##### Street address

Farabi Eye Hospital, Qazvin Square, South Karegar street

##### City

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1336616351

##### Phone

+98 21 5542 1080

##### Email

support@doctorrajabi.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mehran Zarei Ghanavati  
**Position**  
Associate Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
all informations  
**When the data will become available and for how long**  
dates availability after publication  
**To whom data/document is available**  
researchers work at academic centers  
**Under which criteria data/document could be used**  
additional similar patients dates  
**From where data/document is obtainable**  
corresponding researcher  
**What processes are involved for a request to access data/document**  
six months  
**Comments**