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 ·.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 5·% 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
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5542 1080
Email
m-zareigh@sina.tums.ac.ir
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
Tehran
Province
Tehran
Postal code
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

Ophthalmology

Street address

Farabi Eye Hospital. Qazvin Square, South Karegar street

City

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Email

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Person responsible for scientific 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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+98 21 5542 1080

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehran Zarei Ghanavati

Position

Associate Professor

Latest degree

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Other areas of specialty/work

Ophthalmology

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Province

Tehran

Postal code

1336616351

Phone

+98 21 5542 1080

Email

m-zareigh@sina.tums.ac.ir

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