

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Safety evaluation of eye drops containing antibacterial peptides in the treatment of infectious bacterial keratitis

Protocol summary

Study aim

In this study, the safety and effect of the CM11 peptide as eye drops along with standard treatment in patients with bacterial keratitis is being evaluated.

Design

Phase 1 clinical trial has two control and test groups, unblinded, selected, on 10 patients, including 5 patients with standard treatment and 5 patients with standard treatment and combined with peptide.

Settings and conduct

The evaluation will be done in the ophthalmologist's office. The control group receives only standard antibiotic eye drops (ceftazidime + vancomycin). The test group, along with receiving the standard antibiotic eye drops, simultaneously receive the solution containing the peptide. Eye drops are used every 6 hours during the treatment and patients are followed for three months after treatment.

Participants/Inclusion and exclusion criteria

Patients with bacterial keratitis can enter the study if they have consent. Patients with fungal keratitis, bacterial keratitis with widespread eye infection, systemic immunodeficiency, or a history of corneal transplantation are excluded from the study.

Intervention groups

Candidates are divided into two groups of 5 people, control and test. In the control group, they only receive standard antibiotic eye drops (ceftazidime + vancomycin) to treat keratitis. The other group as the test group, along with receiving the standard antibiotic eye drops, simultaneously receive the solution containing the peptide.

Main outcome variables

Removal of bacterial infection, duration of treatment

General information

Reason for update

Acronym

EAPED

IRCT registration information

IRCT registration number: **IRCT20181229042160N4**

Registration date: **2023-12-24, 1402/10/03**

Registration timing: **prospective**

Last update: **2023-12-24, 1402/10/03**

Update count: **0**

Registration date

2023-12-24, 1402/10/03

Registrant information

Name

Mehrdad Moosazadeh Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 4808

Email address

rsr.moosazadeh@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety evaluation of eye drops containing antibacterial peptides in the treatment of infectious bacterial keratitis

Public title

Evaluation of antibacterial peptide eye drops

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with bacterial keratitis caused by
Staphylococcus aureus or Pseudomonas aeruginosa

Having consent to enter the study

Exclusion criteria:

The patient's lack of consent to continue the
examinations Occurrence of any unusual side effects
Infectious keratitis of fungal origin Spread of infection to
other parts of the eye Having systemic
immunodeficiency Having a cornea transplant

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 10

Randomization (investigator's opinion)

Not randomized

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 committee of Baqiyatallah University of
Medical Sciences

Street address

Tissue Engineering Research Center, Baqiyatallah
University of Medical Sciences, Nusrati Alley., South
Sheikh Bahai St., Mulasadra St

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-02-16, 1401/11/27

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.120

Health conditions studied**1****Description of health condition studied**

Bacterial keratitis

ICD-10 code

H16

ICD-10 code description

Keratitis

Primary outcomes**1****Description**

Keratitis infection

Timepoint

3, 7, and 14 days after drug administration

Method of measurement

Microscopic evaluation using Slit lamp

2**Description**

Treatment duration

Timepoint

3, 7, and 14 days after drug administration

Method of measurement

Microscopic evaluation using Slit lamp

Secondary outcomes**1****Description**

Corneal opacity

Timepoint

7, 14, 30 and 90 days

Method of measurement

Microscopic evaluation using Slit lamp

2**Description**

Pain and burning

Timepoint

7, 14, 30 and 90 days

Method of measurement

Microscopic evaluation using Slit lamp

3**Description**

Shedding tears

Timepoint

Macroscopic and microscopic evaluation using Slit lamp

Method of measurement

7, 14, 30 and 90 days

4

Description

Eye redness

Timepoint

7, 14, 30 and 90 days

Method of measurement

Macroscopic and microscopic evaluation using Slit lamp

5

Description

Eye inflammation

Timepoint

7, 14, 30 and 90 days

Method of measurement

Microscopic evaluation using slit lamp

Intervention groups

1

Description

Control group: Treatment using standard antibiotic eye drops (ceftazidime + vancomycin)

Category

Treatment - Drugs

2

Description

Treatment is done using standard antibiotic eye drops (ceftazidime + vancomycin) along with drops containing CM11 antibacterial peptide. For this purpose, eye drops containing 16 µg/ml peptide will be used. During the first week of treatment, patients use peptide drops at 4-hour intervals, and after that, at 6-hour intervals until the infection treatment. The peptide consists of 11 amino acids, synthesized by Morvarid Darou Company in pharmaceutical grade and formulated by Sina Darou Company. This peptide has broad-spectrum antibacterial activity.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Seyed Hashem Daryabari

Street address

Department of Ophthalmology, Baqiyatallah Hospital., Mullasadra St

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 911 320 1959

Email

shdarya50@yahoo.com

2

Recruitment center

Name of recruitment center

Labbafinezhad Hospital

Full name of responsible person

Sepehr Feizi

Street address

Paydar Fard Intersection., Bostan 9., Pasdaran St.,

City

Tehran

Province

Tehran

Postal code

۱۶۶۶۶۳۱۱۱

Phone

+98 912 283 7429

Email

sepehrfeizi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Foolad

Street address

Deputy of Research and Technology, Baqiyatallah University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 912 226 9267

Email

imanifouladi.a@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mehrdad Moosazadeh Moghaddam
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Antibacterial peptides
Street address
Tissue Engineering Research Center, Baqiyatallah
University of Medical Sciences, Nosrati Alley., South
Sheikh Bahai St
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 4808
Email
mm.genetics@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Khosrow Jadid
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Department of Ophthalmology, Baqiyatallah Hospital,
Mullasadra St
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 4808
Email
kh.jadidi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hossein Aghamolaei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Tissue Engineering Research Center, Baqiyatallah
University of Medical Sciences, Nosrati Alley., South
Sheikh Bahai St
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8755 4808
Email
aghamolaei22@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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 data can be presented after the study is done, keeping the identity of the people.

When the data will become available and for how long

Access starts 3 months after results are published.

To whom data/document is available

It is accessible to everyone.

Under which criteria data/document could be used

There is no limit.

From where data/document is obtainable

Using the email listed in the published article.

What processes are involved for a request to access data/document

By email and stating the reason for the request, which will be answered within a maximum of one week process.

Comments

