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

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Iran (Islamic Republic of)

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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., Mullasadra St
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Tehran
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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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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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
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

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Person responsible for scientific inquiries

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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