Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Two Topical (diluted betadine and artificial tears) or (betamethasone and chloramphenicol) versus placebo (two drops of artificial tears) interventions to control clinical symptoms and complications of epidemic keratoconjunctivitis

Protocol summary

Study aim

To compare the therapeutic efficacy of two topical pharmacological interventions versus placebo in the treatment of epidemic keratoconjunctivitis.

Design

A phase 2, randomized, double-blind, parallel-group, controlled clinical trial of 69 patients. Participants will be allocated using block randomization (block size=6) via Random Allocation Software.

Settings and conduct

Patients at Al-Zahra Hospital, Zahedan will undergo I-Tech Vision acuity testing and HAAG Streit BM900 slit-lamp examination by ophthalmology resident. Those with purulent discharge, follicular reaction, and subconjunctival petechiae will be referred to a corneal fellowship for confirmation. After informed consent, patients will receive double-masked, identically packaged treatments: Sina Darou's chloramphenicol 0.5%, betamethasone 0.1%, 1.5% betadine, or Tearlose artificial tears.

Participants/Inclusion and exclusion criteria

Patients with clinically confirmed epidemic viral conjunctivitis, excluding those with Prior treatment, Drug hypersensitivity, Pregnancy, and Thyroid disorders.

Intervention groups

A: Artificial tears + artificial tears B: Diluted betadine + artificial tears C: Betamethasone + chloramphenicol First follow-up: 48 hours post-intervention (with instructions to return if adverse effects occur). Final evaluation: All patients will undergo ophthalmologic examination 2 weeks after study initiation.

Main outcome variables

Clinical symptoms at follow-up; adverse effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250308064985N1**
Registration date: **2025-05-31, 1404/03/10**
Registration timing: **prospective**

Last update: **2025-05-31, 1404/03/10**
Update count: **0**

Registration date

2025-05-31, 1404/03/10

Registrant information

Name
Taher Torabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 54 3321 9917
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t.torabi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Two Topical (diluted betadine and artificial tears) or (betamethasone and chloramphenicol) versus placebo (two drops of artificial tears) interventions to control clinical symptoms and complications of epidemic keratoconjunctivitis

Public title
Effect of topical application of diluted betadine and artificial tears, or betamethasone and chloramphenicol in epidemic keratoconjunctivitis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of epidemic viral conjunctivitis based on: Clinical symptoms (patient-reported): Redness, tearing, and foreign body sensation. Ophthalmologist-confirmed findings: Subconjunctival petechial hemorrhages, purulent discharge, and follicular formation. Willingness to participate in the study (informed consent)

Exclusion criteria:
History of prior treatment Hypersensitivity to iodine Pregnancy Presence of thyroid disorders

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization type is simple randomization. Using a random number table, participants will be assigned to groups until the target sample size in each group is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
Allocation concealment will be implemented using opaque, sealed, sequentially numbered envelopes. The procedure will be as follows: A random sequence is first generated. The allocation sequence is recorded on separate cards. Each card is placed inside an envelope in sequential order. The envelopes are numbered externally and stored in a box in sequential order. Upon enrollment, participants will select an envelope in the order of their recruitment, thereby revealing their assigned intervention group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of ZahedanUniversity of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr Hesabi Square, Zahedan, Iran

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2025-03-02, 1403/12/12

Ethics committee reference number
IR.ZAUMS.REC.1403.472

Health conditions studied

1

Description of health condition studied
Epidemic keratoconjunctivitis

ICD-10 code
B30.0

ICD-10 code description
Keratoconjunctivitis due to adenovirus

Primary outcomes

1

Description
Ocular signs and symptoms on examination

Timepoint
Baseline, day 2, and week 2 post-intervention.

Method of measurement
Ophthalmic examination

2

Description
Adverse effects

Timepoint
Baseline, day 2, and week 2 post-intervention.

Method of measurement
Ophthalmic examination

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Receives two Tearlose artificial tears (Sina Darou, Tehran).
Category
Placebo

2

Description
Intervention group: Receives diluted betadine eye drop plus of artificial tears eye drop (Sina Darou, Tehran).
Category
Treatment - Drugs

3

Description
Intervention group: Receives 0.1% betamethasone eye drop and 0.5% chloramphenicol eye drop (Sina Darou, Tehran).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital, Zahedan
Full name of responsible person
Taher Torabi
Street address
Shahid Motahari BLV, Zahedan,
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T.torabi@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Alireza Ansari Moghadam
Street address
Dr Hesabi Square, Zahedan.
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+98 54 3337 2151
Email
zaums.research@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Taher Torabi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Data on demographic and clinical information of participants.
When the data will become available and for how long
In the second half of 1404.
To whom data/document is available
The Vice Chancellor for Research of Zahedan University of Medical Sciences will determine it.
Under which criteria data/document could be used
The Vice Chancellor for Research of Zahedan University of Medical Sciences will determine it.
From where data/document is obtainable
The Vice Chancellor for Research of Zahedan University of Medical Sciences.
What processes are involved for a request to access data/document
Sending a written request to the project implementers or obtaining permission from the Vice Chancellor for Research of Zahedan University of Medical Sciences.
Comments