Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of a 1% azithromycin eye drops treatment on signs and symptoms of blepharitis

Protocol summary

Study aim
Determining the effect of azithromycin 1% treatment on the signs and symptoms of blepharitis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. It will be done by blocking method for randomization.

Settings and conduct
This study is performed in Razi Hospital of Birjand, South Khorasan Province. 90 patients are randomly divided into two groups: 1% azithromycin or erythromycin. Then, the signs and symptoms of blepharitis in patients before and 4 weeks after treatment will be evaluated by the study leader without knowing the type of medication received by the patient.

Participants/Inclusion and exclusion criteria
Patients with blepharitis will be referred to the ophthalmology clinic of Razi Hospital in Birjand in 1400. Admission requirements :. Patients with anterior blepharitis between the ages of 18 and 80 and patients with eye injuries and infections, non-dry eye inflammation, surgery, and eye trauma will be excluded in the last 6 months.

Intervention groups
Patients with blepharitis referred to an ophthalmology clinic will be randomly divided into two groups receiving 1% azithromycin (topical twice daily for 4 days) and erythromycin (topical twice daily for 4 days).

Main outcome variables
Clinical signs and symptoms of blepharitis include eye irritation, itching and burning of the eyelids, eye discomfort after working with a computer, a feeling of heaviness in the eyelids, discharge on the eyelashes, a feeling of dry eyes, sticking of the eyelids when waking up and redness of the eyes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190618043934N9**
Registration date: **2021-04-14, 1400/01/25**
Registration timing: **prospective**

Last update: **2021-04-14, 1400/01/25**
Update count: **0**

Registration date
2021-04-14, 1400/01/25

Registrant information

Name
Zabihullah Mohaghegh

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
2021-04-21, 1400/02/01

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of a 1% azithromycin eye drops treatment on signs and symptoms of blepharitis

Public title
The effect of azithromycin 1 on the signs and symptoms of blepharitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with anterior blepharitis Age 18 to 80 years
Exclusion criteria:
Eye injuries and infections Non-dry eye inflammation, surgery Eye trauma in the last 6 months
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be randomly divided into two intervention groups receiving azithromycin 1% (group A) and the control group receiving erythromycin (group B) by simple blocking method. Patients with the above conditions in two groups are randomly entered into one of the two intervention or control groups by blocking method (quadruple blocks). Thus, various quadrilateral blocks were created (AABB, BBAA, ABAB, BABA, ABBA and BABA). One of these blocks will be randomly selected and patients will be divided into one of two groups A or B. Then randomization was performed for other patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome Assessor: The ward nurse, without knowing the type of medication received, questions the patients and records them in the relevant checklist. Participants in the study without knowing the medication received for the treatment of blepharitis, which is the gold standard treatment or the new treatment for blepharitis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Ghaffari Blvd
City
Birjand
Province
South Khorasan
Postal code
9717811674
Approval date
2021-03-01, 1399/12/11
Ethics committee reference number
IR.BUMS.REC.1399.532

Health conditions studied

1

Description of health condition studied
Blepharitis
ICD-10 code
H01.0
ICD-10 code description
Blepharitis

Primary outcomes

1

Description
Clinical signs and symptoms of blepharitis include eye irritation, itching and burning of the eyelids, eye discomfort after working with a computer, a feeling of heaviness in the eyelids, discharge on the eyelashes, a feeling of dry eyes, sticking of the eyelids when waking up and redness of the eyes.
Timepoint
Before and after the intervention (4 weeks after the intervention)
Method of measurement
Self-reported using the standard OcularSurfaceDiseaseIndex questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving azithromycin 1% eye drops (manufactured by Sina Daru Pharmaceutical Company-Iran) topically twice a day for 4 days.
Category
Treatment - Drugs

2

Description
Control group: Patients receiving topical erythromycin eye ointment (manufactured by Iran Najo_Iran Pharmaceutical Company) 2 times a day for 4 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital_Birjand
Full name of responsible person
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Sponsors / Funding sources

1

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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
Birjand 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
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available