

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

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

Armin Forghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

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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

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Member of the Faculty

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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