

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Azithromycin and Pyrimethamine/sulfadiazine Treatment in Ocular Toxoplasmosis

Protocol summary

Summary

This controlled, randomized, single-blind study included patients diagnosed clinically with ocular toxoplasmosis, as defined by the presence of visual complaints and an area of focal necrotizing retinochoroidal lesion appearing as a whitish yellow region with a blurred margin plus or minus the accompaniment of an old lesion. Patients were recruited from the Nikookari Hospital Uveitis Clinic, Tabriz, Iran. Patients consented to participation in the study, and it was approved by the ethics committees of the hospital and the Tabriz University of Medical Sciences. Of the 72 patients enrolled in the study, all completed follow-up. 36 patients were treated with the classic regimen consisting of Pyrimethamine and Sulfadiazine, and 36 were treated with Azithromycin. An initial loading dose of 100 mg of Pyrimethamine, followed by a 50-mg dose daily, and sulfadiazine with loading dose of 2 gr followed by 500-mg dosing every 6 hours, and 5 mg of Folinic acid daily as the classic treatment protocol was used. In the other group, 1 tablets of Azithromycin 250 mg daily was used. In both groups, drugs were continued for 6 weeks; oral Prednisolone was administered at 1 mg/kg daily starting from the third day of therapy, and the dose was tapered over 2 weeks. Response to treatment was identified as sharpening of the lesion border with or without hyperpigmentation and resolution of vitreous inflammation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702146568N2**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Leila Alizadeh ghavidel

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1655 1332

Email address

alizadehl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2017-02-26, 1395/12/08

Expected recruitment end date

2019-02-21, 1397/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Azithromycin and Pyrimethamine/sulfadiazine Treatment in Ocular Toxoplasmosis

Public title

Comparison of Azithromycin and Pyrimethamine/sulfadiazine Treatment in Ocular Toxoplasmosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Presence of the retinal lesion at least 500 micrometers outside the center of the macula. 2. Lack of history of allergic reaction to the drugs used in this study. 3. Lack of any other ocular disease. Exclusion criteria: 1. Visual acuity (VA) of lesser than 20/200 2. Location of the lesion within the center (500 micrometers) of the macula 3. Development of an allergic reaction to the medication 4. Leukopenia (white blood cell count lesser than 5000) or platelet count lesser than 120 000/ml

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

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 Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code

Approval date

2017-02-09, 1395/11/21

Ethics committee reference number

IR.TBZMED.REC.1395.1173

Health conditions studied

1

Description of health condition studied

Retinochoroiditis

ICD-10 code

B58.0

ICD-10 code description

Toxoplasma Oculopathy

Primary outcomes

1

Description

The clinical improvement

Timepoint

One week, one month and three months after the first dose

Method of measurement

Ophthalmoscope

Secondary outcomes

1

Description

Visual acuity

Timepoint

One week, one month and three months after treatment.

Method of measurement

Using the Snellen chart

2

Description

The recurrence rate

Timepoint

هر 6 ماه تا 2 سال

Method of measurement

Ophthalmoscope

Intervention groups

1

Description

Group A: azithromycin 500 mg on the first day and then 250 mg daily

Category

Treatment - Drugs

2

Description

Group B: pyrimethamine 100 mg the first day and 50 mg sulfadiazine 500 mg every 6 hours for 2 days then 1 mg a day among a number folinic acid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Nikukari hospital

Full name of responsible person

Leila Alizadeh ghavidel

Street address

Nikukari hospital, Abbasi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Leila Alizadeh ghavidel

Position

Assistant Professor of Immunology eyes

Other areas of specialty/work

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Full name of responsible person

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Position

Assistant Professor of Immunology eyes

Other areas of specialty/work

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City

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Phone

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty