Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of therapeutic effects of Azitromaycin and Cotrimoxazole in patients with ocular Toxoplasmosis .

Protocol summary

Summary

This study is a randomized controlled trial, comparing the therapeutic effect of Azithromycin and Co-trimoxazole in the treatment of patients with ocular toxoplasmosis referred to Farabi eye hospital. Thirty patients are randomized 1:1 to each of the treatment groups. Clinical examination, Fundus photography, Autofluorescence and Infrared are performed before the treatment and in the third and sixth weeks after treatment and at the completion of therapy. Adverse effects of medications in both groups are registered. At the completion of treatment, the change in the size of lesions, improvement of visual acuity, medication side effects and vitreous changes will be compared between the two groups. Inclusion criteria were patients with ocular toxoplasmosis aged 15 years or above with positive anti-toxoplasma IgG antibody test. Exclusion criteria were pre-existing retinal diseases and antibiotic usage within the last three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401299820N5**
Registration date: **2014-03-11, 1392/12/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Alireza Lashay

Name of organization / entity

Eye research center

Country

Iran (Islamic Republic of)

Phone

+98 21 5512 1002

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Of Siences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of Azitromaycin and Cotrimoxazole in patients with ocular Toxoplasmosis .

Public title

Comparison of therapeutic effects of Azitromaycin and cotrimoxazole in patients with ocular toxoplasmosis .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with diagnosis of ocular toxoplasmosis with positive serologic test; patients older than 16 years old; no underline diseases(such as diabetic retinopathy or uveitis). Exclusion criteria: patients under 16 years old; any related systemic or ocular diseases in particular immunodeficiency diseases.

Age

No age limit

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran, Enghelab Square, Qazvin Square, Farabi Eye Hospital
City
Tehran
Postal code
1336616351
Approval date
2013-09-23, 1392/07/01
Ethics committee reference number
ERC/262

Health conditions studied

1

Description of health condition studied
ocular toxoplasmosis
ICD-10 code
B58.0
ICD-10 code description
Toxoplasma Oculopathy

Primary outcomes

1

Description
Sharpening of Lesion Border
Timepoint
0, weeks 3 to 4, end of treatment
Method of measurement
Clinical Examination, Fundus Photography

2

Description
Lesion Size
Timepoint
0, weeks 3 to 4, end of treatment
Method of measurement
Autoflurescence, Infrared (Image J)

3

Description
Drug Side Effects
Timepoint
0, weeks 3 to 4, end of treatment
Method of measurement
CBC diff, Billi (T, D)

4

Description
Response to Treatment
Timepoint
weeks 3 - 4
Method of measurement
Clinical Examination

5

Description
Vissual Improvment
Timepoint
0, weeks 3 to 4, end of treatment
Method of measurement
Snellen chart

Secondary outcomes

1

Description
Intera ocular Pressure
Timepoint
weeks 0,2 and end of treatment
Method of measurement
goldman tonometery

2

Description
vitritis
Timepoint
weeks 0,2 and end of treatment
Method of measurement
fundus photography and clinical examination

Intervention groups

1

Description
Cotrimoxazole Tablet 800 mg , bid for 6-12 weeks, Tablet Folic Acid 1 mg daily for 6-12 weeks , Tablet Prednisolon 50 mg from third day to 2 weeks.
Category
Treatment - Drugs

2

Description
Cap Azithromycin 500 mg first day, then 250 mg daily, and Prednisolon tab 50 mg daily from third day to 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Eye Hospital
Full name of responsible person
Dr Najaf Parandin
Street address
Tehran, Enghelab Square , Qazvin Square, Farabi Eye Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Farabi Eye Hospital, Farabi Eye Reaserch Center
Full name of responsible person
Dr. Ali Sadeghi Tari
Street address
Tehran, Qazvin Square, Farabi Eye Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Farabi Eye Hospital, Farabi Eye Reaserch Center
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
Farabi Eye Hospital
Full name of responsible person
Dr. Najaf Parandin
Position
resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Farabi Eye Hospital
Full name of responsible person
Dr. Alireza lashay
Position
Professor
Other areas of specialty/work
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Person responsible for updating data

Contact
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Farabi Eye Hospital
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Dr. Najaf Parandin
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Resident

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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