

# 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

lashay@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Of Sciences

##### 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

Autofluorescence, 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

Visual Improvement

#### Timepoint

0, weeks 3 to 4, end of treatment

#### Method of measurement

Snellen chart

## Secondary outcomes

### 1

#### Description

Intra ocular Pressure

#### Timepoint

weeks 0,2 and end of treatment

#### Method of measurement

goldman tonometry

### 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**

**Street address**

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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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**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*