

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The efficacy of Eplerenon drug in patient with Acute CSCR (Central SerousChorioretinopathy)

#### Protocol summary

##### Study aim

determination of eplerenone treatment efficacy in CSR patients

##### Design

Interventional study with control group, Two blinded, randomized, Factorial groups, 40 patients

##### Settings and conduct

Patients with CSR were randmoly (two blinded) divided into "treatment with eplrenon" and placebo groups. in treatment group, for first week 25 and for next 3 weeks 50mg eplrenon was administered.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute onset of disease (less than 3 months) without history of previous treatments including treatment with drugs, PDT, Photocuagulation LASER absence of choroidal neovascularization, polypoidal choroidal vasculopathy absence of any pathology and impaired vision in other eye absence of ophthalmic eye pathology such as Glaucoma, Retinal disease and uveitis not taking corticostroids agents normal kidney lab tests for "treatment" group

##### Intervention groups

Patients with Central Serous Chorioretinopathy which take eplerenone treatment (50mg/daily for the first week and then 25mg/daily for the net three weeks) Patients with Central Serous Chorioretinopathy which take placebo treatment (every day one placebo)

##### Main outcome variables

Best corrected visual acuity; central macular thickness; macular volume; choroid thickness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180825040860N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

##### Registration date

2019-09-28, 1398/07/06

##### Registrant information

###### Name

Hamidreza Jahanbani-Ardakani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3222 5034

###### Email address

hamidreza\_jahanbaniardakani@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of Eplerenon drug in patient with Acute CSCR (Central SerousChorioretinopathy)

##### Public title

The efficacy of Eplerenon drug in patient with Acute CSCR (Central SerousChorioretinopathy)

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Acute onset of disease (less than 3 months) without history of previous treatments including treatment with drugs, PDT, Photocoagulation LASER absence of any pathology and impaired vision in other eye absence of ophthalmic eye pathology such as Glaucoma, Retinal disease and uveitis not taking corticosteroids agents normal kidney lab tests for "treatment" group having consent to participating in study

**Exclusion criteria:**

does not having Consent to participating in study  
Younger than 18 years old suffering from any ocular or kidney disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

we divided patients randomly (with Dr.Saghaei's software) into 2 groups; 20 participants in "treatment group" and 20 participants in "placebo group".

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In the current study, neither patients nor physicians were not aware that every patient has been categorized in the treatment group or placebo group. The participating individuals were randomly categorized in treatment or placebo groups by using Dr. Saghaei software. after diagnosis, the patients were randomly divided into two groups (Placebo/treatment). the physician does not know the patients are in which group during visiting and follow-up. also none of the patients knows their classification until end of study. After the disease was diagnosed by specialist and resident of ophthalmology, participants were referred to secretary an he/she delivered placebo or drug to participants. In following up visits, results of tests were gathered by secretary and after doing anonymously, the results were delivered to an epidemiologist. after analysis, it was cleared that each data and analysis were related to each group. All of the patients were awarded regarding their classification (placebo or treatment group) after the study was done.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**

Ethical Committee of Isfahan University of Medical Sceinces

**Street address**

Hezar Jareeb str., Azadi Sqr.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8974673461

**Approval date**

2019-02-17, 1397/11/28

**Ethics committee reference number**

IR.MUI.MED.REC.1397.242

## Health conditions studied

1

**Description of health condition studied**

Central Serous Chorioretinopathy

**ICD-10 code**

H35.71

**ICD-10 code description**

Central serous chorioretinopathy

## Primary outcomes

1

**Description**

Best Corrected visual aquity

**Timepoint**

before and one month after initiation of intervention

**Method of measurement**

snellen chart

2

**Description**

Central macular thickness

**Timepoint**

before and one month after initiation of intervention

**Method of measurement**

optical coherence topography

3

**Description**

Macular volume

**Timepoint**

before and one month after initiation of intervention

**Method of measurement**

optical coherence topography

## 4

### Description

Choroidal thickness

### Timepoint

before and one month after initiation of intervention

### Method of measurement

optical coherence topography

## Secondary outcomes

### 1

#### Description

adverse effects of eplerenon

#### Timepoint

during intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: for patients of treatment group, Eplerenon was initiated. in the first week, 25 mg daily and for the three next weeks, 50 mg daily was administered.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: for patients of control group, placebo was administered for 4 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Feiz eye hospital

##### Full name of responsible person

Alireza Dehghani

##### Street address

Qods square; feiz eye hospital

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8149644874

##### Phone

+98 31 3445 2031

##### Email

dehghani@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjooy Javanmard

##### Street address

Azadi Square, Hezar Jareeb Street, Esfahan University of Medical Sciences, Building No. 4

##### City

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##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3668 5149

##### Email

research@mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Mohammad Tohidi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Ophthalmology

##### Street address

Feiz Eye Hospital, Qods Sq, Isfahan

##### City

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##### Province

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##### Postal code

8149644874

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**Email**

dr.tohidi1387@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Dehghani

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Jahanbani Ardakani

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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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