

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, Photocagulation 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)

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+98 35 3222 5034

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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 Sciences

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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