Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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, Photocuagulation 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 corticostroids 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 randomely 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 secretory an he/she delivered placebo or drug to participants. In following up visits, results of tests were gathered by secretory 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

Isfehan

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 topogrphy

3

Description

Macular volume

Timepoint

before and one month after initiation of intervention

Method of measurement

optical coherence topogrphy

4

Description
Choroidal thickness
Timepoint
before and one month after initiation of intervention
Method of measurement
optical coherence topogrphy

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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