Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral eplerenone in the management of Acute Central Serous Chorioretinopathy

Protocol summary

Study aim
Evaluation of the effect of oral eplerenone in the management of Acute Central Serous Chorioretinopathy

Design
A clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on about 36 patients.

Settings and conduct
Patients who refer to Baqiyatullah Clinic due to acute central serous chorioretinopathy will be included in the study according to the entry and exit criteria. Patients will be randomly divided into intervention and control groups. At first, each patient will undergo visual acuity evaluation and SD-OCT and clinical examinations. The intervention group treated with eplerenone and the control group will receive Eye vit plus tablets. Patients will be followed up in 1, 2, 3 months after the start of treatment by measuring BCVA and SD-OCT. Whenever the disease improves during the treatment period, the drug will be discontinued. Then the measured data in two groups of case and control are analyzed and compared with appropriate statistical tests.

Participants/Inclusion and exclusion criteria
Acute central serous chorioretinopathy before twelve weeks Acute central serous chorioretinopathy for the first time

Intervention groups
Intervention group: Patients in the case group will be treated with eplerenone oral tablets, at the rate of 50 mg per day for 12 weeks. Follow-up of patients in 1, 2, 3 months after the start of treatment will be done by measuring BCVA and SD-OCT. Whenever the disease improves during the treatment period, the drug will be discontinued. Control group: Patients of the case group will be treated with eye vit plus oral tablets, one tablet daily for 12 weeks. The follow-up of the patients will be the same as the intervention group.

Main outcome variables
Primary outcome measures will include comparison of BCVA, SD-OCT and clinical examinations between treatment and control groups and at all time points.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220423054621N1**
Registration date: **2024-06-24, 1403/04/04**
Registration timing: **prospective**

Last update: **2024-06-24, 1403/04/04**
Update count: **0**

Registration date
2024-06-24, 1403/04/04

Registrant information

Name
mona alvandimanesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 921 241 8042

Email address
monaalvandimanesh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-29, 1403/04/09

Expected recruitment end date
2024-09-04, 1403/06/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of oral eplerenone in the management of Acute Central Serous Chorioretinopathy

Public title
Evaluation of the effect of oral eplerenone in the management of Acute Central Serous Chorioretinopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of acute central serous chorioretinopathy before twelve weeks Diagnosis of acute central serous chorioretinopathy for the first time

Exclusion criteria:
Chronic CSCR (duration of visual symptoms more than 12 weeks) Recurrent CSCR (patients with a history of one or more previous CSCR attacks) Choroidal neovascularization (CNV) detected by FA, ICGA, or OCT angiography (OCT-A) Any treatment for retinal disease (including intravitreal injections, photodynamic therapy, laser photocoagulation, vitrectomy) History of other retinal disorders (including age-related macular degeneration, choroidal neovascularization, diabetic retinopathy, uveitis, or pathological myopia) The presence of any other systemic disease for which eplerenone is contraindicated (such as severe renal, cardiac or hepatic failure, pregnancy, baseline serum potassium more than 0.5 mEq/L simultaneous administration of potassium-sparing diuretics, potassium supplements, inhibitors angiotensin converting enzyme or angiotensin receptor blockers)

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done using the random blocking method (blocks of four). The possible blocks are as follows: 1- AABB, 2- ABAB, 3- BABA, 4- BBAA, 5- BAAB, 6- ABBA. In this step, numbers (1 to 6) will be randomly selected using the table of random numbers. and this work is repeated 10 times until the sample volume is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The drugs of the two groups will be similar in terms of shape, color and packaging (the pharmaceutical company has been asked to make a placebo in the same packaging as the drug under study) and the patients and also the person evaluating the consequences of the status of assignment to the treatment groups And they will not know the hypothesis of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of baghiatallah University of Medical Sciences

Street address
Vanak Sq Mollasadra Ave

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2024-01-13, 1402/10/23

Ethics committee reference number
IR.BMSU.BAQ.REC.1402.088

Health conditions studied

1

Description of health condition studied
Acute Central Serous Chorioretinopathy

ICD-10 code
H35.7

ICD-10 code description
Separation of retinal layers

Primary outcomes

1

Description
Best corrected visual acuity (BCVA)

Timepoint
At the beginning of the study, one month, two months and three months later

Method of measurement
Tumbling E” eye chart

2

Description

Central Macular Thickness (CMT)

Timepoint

At the beginning of the study, one month, two months and three months later

Method of measurement

Use of SD-OCT device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the case group will be treated with eplerenone oral tablets, at the rate of 50 mg per day for 12 weeks. Follow-up of patients in 1, 2, 3 months after the start of treatment will be done by measuring BCVA and SD-OCT. Whenever the disease improves during the treatment period, the drug will be discontinued.

Category

Treatment - Drugs

2

Description

Control group: The patients of the case group will be treated with eye vit plus oral tablets (OPD Pharma), one pill per day for 12 weeks. Follow-up of patients in 1, 2, 3 months after the start of treatment will be done by measuring BCVA and SD-OCT. Whenever the disease improves during the treatment period, the drug will be discontinued.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyat Allah Clinic

Full name of responsible person

Mona Alvandimanesh

Street address

Baqiyatullah Al-Azam Hospital ,Mulla Sadra St. , Vanak Square

City

Tehran

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1435915371

Phone

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Email

Dr.Samadinia@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Nematollah Jonaidi

Street address

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Phone

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Email

dr.samadinia@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mona Alvandimanesh

Position

Ophthamology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Mona Alvandimanesh

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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
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how long
Access to the data is possible immediately after the result is determined

To whom data/document is available
The data will be available to researchers

Under which criteria data/document could be used
The information can be used for further study and research

From where data/document is obtainable
Responsible for the project's scientific information monaalvandimanesh@gmail.com

What processes are involved for a request to access data/document
After sending the request, the information will be available to the applicant within three days

Comments