Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of Eplerenone effects on the imaging findings in acute central serous chorioretinopathy: a randomized clinical trial

Protocol summary

Study aim

Comparison of changes in choroidal perfusion in macula area in macular-OCTA and choroidal thickness in EDI-OCT before and after eplerenone tablet use in acute CSCR.

Design

In this clinical trial patients are simply randomized in double-blinded way in 2 parallel groups of 20 numbers of control (Placebo) and intervention (Eplerenone)

Settings and conduct

After confirmation of CSCR and Filling Informed consent, demographic data and clinical examinations like BCVA are documented then macular OCT-A, ONH OCT-A, macular EDI-OC will be done. Choroidal thickness in fovea macula perfusion vessel density flow index in central 3 mm and radial peri-papillary capillary (RPC) vessel density and CMT and SRF height are assessed. Simple double-blinded randomization make patients in 2 placebo and intervention groups. For all intervention groups we use eplerenone for 3 months . All parameters are repeated documented and re-analysed one and three months after treatment and finally analysis are done

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients that are referred to khatam eye hospital emergency or clinics with the definite first episode of acute CSCR under age of 18 No history of intraocular diseases No contraindication of eplerenone use Exclusion criteria: Any finding making the diagnosis of CSCR suspiscious Any intraocular disease happening Any eplerenone contraindication happening

Intervention groups

Intervention group are patients under treatment of eplerenone 25 mg BID for 3 months.

Main outcome variables

Best corrected visual aquity (BCVA), central macular thickness, subretinal fluid height, subfoveal choroidal thickness, vessel density, flow index in central 3 mm and also in optic nerve head at the beginning, 1 month and 3 months after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191116045458N1**
Registration date: **2020-05-12, 1399/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-12, 1399/02/23**
Update count: **0**

Registration date

2020-05-12, 1399/02/23

Registrant information

Name
Roozbeh Asghari
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Eplerenone effects on the imaging findings in acute central serous chorioretinopathy: a randomized clinical trial

Public title
Assessment of Eplerenone effects on the imaging findings in acute central serous chorioretinopathy: a randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients that are referred to khatam eye hospital emergency room or clinics with the definite first episode of acute CSCR diagnosis with decreased visual acuity or metamorphopsia for less than 3 months No history of intraocular diseases No contraindication for eplerenone use (renal, heart or liver failure, pregnancy, breast feeding, K serum level more than 5 mg/dl, ACEI ,ARB or k-sparing diuretic use, hypertention,type 2 DM with microalbuminuria, use of azoles and clarithromycin).
Exclusion criteria:
any finding making CSCR diagnosis suspicious during treatment detection of any intraocular disease during treatment detection of any contraindication of Eplerenone during treatment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is done as individual units. closed classified envelopes is used . Making series is done by randomized table of numbers in www.randomization.com
Blinding (investigator's opinion)
Double blinded
Blinding description
After definite diagnosis, researcher will refer participants to Statistician specialist for simple randomization by closed classified envelopes into 2 control and intervention groups. File number is obvious for patients, researcher and Statistician specialist. Grouping of patients is just obvious for secretory of Statistician specialist and is hidden for patients, researcher and Statistician specialist. After collecting and during data entrance, Statistician specialist will match the file number and groups and data analysis will be done.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad. Vakil abad Blvd., Bahonar Ave., ferdowsi university, faculty of medical sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2019-05-07, 1398/02/17
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.475

Health conditions studied

1

Description of health condition studied
Acute central serous chorioretinopathy
ICD-10 code
H35.719
ICD-10 code description
Central serous chorioretinopathy, unspecified eye

Primary outcomes

1

Description
Choroidal perfusion
Timepoint
Before starting treatment, 1 month later and 3 months later
Method of measurement
According to parameters including subfoveal choroidal thickness, vessel density and flow rate in superficial , deep and choriocapillary level in 3mm center of macula.

Secondary outcomes

1

Description
Best corrected visual acuity
Timepoint

Before treatment starting, 1 month and 3 months later

Method of measurement

Examination by optometrist

2

Description

Central macula thickness

Timepoint

Before treatment starting, 1 month and 3 months later

Method of measurement

Performing OCT

3

Description

Subretinal fluid height

Timepoint

Before treatment starting, 1 month and 3 months later

Method of measurement

Performing OCT

4

Description

Optic nerve head perfusion

Timepoint

Before treatment starting, 1 month and 3 months later

Method of measurement

Vessel density flow index in OCT Angiography

Intervention groups

1

Description

Intervention group: patients with definite diagnosis of acute CSCR will be under treatment of Eplerenone 25 mg BID treatment for 3 months

Category

Treatment - Drugs

2

Description

Control group: will get placebo tablets BID for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam eye hospital

Full name of responsible person

Ghodsieh Zamani

Street address

Mashad, Gharani blvd., between Aboutaleb and Ferdowsi square. Khatam eye hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Eslami

Street address

Daneshgah Ave., beside Hoveizeh cinema, Gharashi apartment, Deputy of Research and Technology

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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

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Ghodsieh Zamani
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
all information and details will be available for general population
When the data will become available and for how long
6 months after final acceptance
To whom data/document is available
all academic and scientific organizations
Under which criteria data/document could be used
Any analysis is acceptable
From where data/document is obtainable
request to my E-mail: Asgharir961@mums.ac.ir
What processes are involved for a request to access data/document
data will be reachable maximum 1 month after request

by E-mail

Comments