

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 suspicious 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

Roosbeh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3217 4274

Email address

asgharir961@mums.ac.ir

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	Parallel
Public title Assessment of Eplerenone effects on the imaging findings in acute central serous chorioretinopathy: a randomized clinical trial	Other design features
Purpose Treatment	Secondary Ids empty
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	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
Age From 18 years old	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
Gender Both	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.
Phase 3	Secondary outcomes 1 Description Best corrected visual acuity Timepoint
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 secretary 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	

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Fax

+98 51 3724 5363

Email

KH.PR@mums.ac.ir

Web page address

<http://khatam.mums.ac.ir/>

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

vcresraech@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

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

Street address

Gharani Blvd., between Aboutaleb intersection and Ferdowsi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Fax

+98 51 3724 5363

Email

ZamaniGH@mums.ac.ir

Web page address

<http://khatam.mums.ac.ir/>

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

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Ghodsieh Zamani

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Person responsible for updating data

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

Street address

Garani Blvd., between Aboutaleb intersection and Ferdowsi square. khatam eye hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Fax

+98 51 3724 5363

Email

ZamaniGH@mums.ac.ir

Web page address

<http://khatam.mums.ac.ir/>

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