Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Oral mineralocorticoid-receptor antagonist vs 0.3 % nepafenac for the treatment of acute central serous chorioretinopathy: a prospective, randomized comparative study

Protocol summary

Study aim

compare two treatments (oral eplerenone and topical nepafenac) in the resolution of acute central serous chorioretinopathy

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site. sample size 55 in each group, 110 in total.

Settings and conduct

Multicentric. Pakistan. Retina clinic of a tertiary care dedicated eye care setup. The person assessing the scans of the retina and the technician who will assess the vision will be blinded. Trail statistician, data entries, technician, pharmacist and staff will be blinded.

Participants/Inclusion and exclusion criteria

Participants were eligible if they were aged 18-60 years with acute central serous chorioretinopathy. Acute central serous chorioretinopathy was defined by the presence of subretinal fluid on optical coherence tomography (OCT) and visual symptoms for < 12 weeks' duration. Exclusion criteria were the presence of chronic central serous chorioretinopathy, duration of visual symptoms more than 12 weeks, diffuse retinal pigment epithelial changes or recurrent central serous chorioretinopathy , presence of choroidal neovascular membrane identified by OCT and confirmed on fundus angiography; any treatment for retinal disease (including intravitreal injections, photodynamic therapy, laser photocoagulation, vitrectomy), history of other retinal disorders (including age-related macular degeneration, diabetic retinopathy, uveitis or pathologic myopia).

Intervention groups

55 patients will be given topical nepafenac and 55 will be given oral eplerenone.

Main outcome variables

Resolution of visual acuity i.e. vision and the resolution of subretinal fluid as seen on the optical coherence tomography scans.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240404061413N1**
Registration date: **2024-05-01, 1403/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-01, 1403/02/12**
Update count: **0**

Registration date

2024-05-01, 1403/02/12

Registrant information

Name

Adnan Saleem

Name of organization / entity

Amanat Eye Hospital

Country

Pakistan

Phone

+92 51 8438021

Email address

doctoradnansaleem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2025-04-15, 1404/01/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral mineralocorticoid-receptor antagonist vs 0.3 % nepafenac for the treatment of acute central serous chorioretinopathy: a prospective, randomized comparative study

Public title

[comparing two treatments in resolving a retinal/eye disorder] Per oral Eplerenone and topical nepafenac are being compared in the treatment of central serous chorioretinopathy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

acute central serous chorioretinopathy

Exclusion criteria:

chronic central serous chorioretinopathy
contraindications to oral eplerenone or topical nepafenac
retinal or choroidal pathologies severe ocular disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned (1:1) to either the 50 mg eplerenone (Epler- Platinum Pharmaceuticals) or 0.3 % nepafenac (Ilevro–Novartis) group by a trial statistician through a password-protected system online. Allocation was stratified by best corrected visual acuity and hospital(s). All participants, care teams, outcome assessors, pharmacists, and members of the trial management group were masked to the treatment allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Prescribing surgeon/doctor, optometrist assessing visual acuity, pharmacists (enclosed coded box of same dimensions), retinal scan technician were masked to the treatment allocation. The person assessing the primary and secondary outcomes would not be aware what treatment has been given to the patients. Oral eplerenone is taken per oral whereas nepafenac is being given topically. Both are effective treatments in acute central serous chorioretinopathy. Both interventions have different routes of administration. Eplerenone is a tablet whereas nepafenac a drop formulation. The main study team are blind to the participants chosen treatment. the trial statistician who wasn't involved in data collection has information on allocated treatment for the ethics committee and monitoring.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Al-Shifa trust eye hospital

Street address

jhelum road rawalpindi

City

Rawalpindi

Postal code

42000

Approval date

2023-12-01, 1402/09/10

Ethics committee reference number

ASTEH 2023/02/101

Health conditions studied

1

Description of health condition studied

Acute central serous retinopathy in a eye retinal disorder which involves by serous retinal detachment (SRD) due to one or more leakage areas from the choroid through a defect in the retinal pigment epithelium (RPE), and a dome shaped serous pigment epithelial detachment (PEDs).

ICD-10 code

H35.71

ICD-10 code description

Central serous chorioretinopathy

Primary outcomes

1

Description

Primary outcome measures were best corrected visual acuity comparisons between the treatment group (oral eplerenone & topical nepafenac) in the study eye at every visit.

Timepoint

Before intervention and 6, 12 and 24 weeks after either

intervention.

Method of measurement

optometrist/technician will measure the vision with a Snellen chart as letters read with prescription glasses , if any.

2

Description

Primary outcome measures were subretinal fluid height measurements between the treatment group (oral eplerenone & topical nepafenac) in the study eye at every visit.

Timepoint

Before intervention and 6, 12 and 24 weeks after either intervention.

Method of measurement

optical coherence tomography

3

Description

Primary outcome measures were sub-foveal choroidal thickness measurements between the treatment group (oral eplerenone & topical nepafenac) in the study eye at every visit.

Timepoint

Before intervention and 6, 12 and 24 weeks after either intervention.

Method of measurement

optical coherence tomography

Secondary outcomes

1

Description

Secondary outcome was serum potassium level evaluation in oral eplerenone group.

Timepoint

Before intervention and 6 weeks.

Method of measurement

Serum potassium levels will be measured with a lab kit at six weeks to assess any derangements.

2

Description

Secondary outcome were topical nepafenac drug tolerance evaluated at each visit.

Timepoint

Before intervention and 6, 12 , 24 weeks after either intervention

Method of measurement

Slit lamp examination will be done to determine any possible side effects related to topical nepafenac (primarily corneal and conjunctival side effects)

Intervention groups

1

Description

Intervention group:1. Oral eplerenone 50 mg in two divided doses (25 mg tablet twice day)12 hours apart for 6 weeks will be given. Medicine taken after meals at the same time each day. Epler (platinum pharma, Pakistan)

Category

Treatment - Drugs

2

Description

Intervention group: 2. Topical nepafenac 0.3 % will be given. one drop in the morning in the affected eye in the lower cul de sac. Patient will be advised to keep the eye closed for 30 seconds. Nevanac 0.3 % eye drops by Alcon/Novartis Group USA.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Shifa Trust Eye hospital

Full name of responsible person
Ahmad Hasan Alizai

Street address
Jhelum road

City
Rawalpindi

Postal code
42000

Phone
+92 321 5180996

Email
alizai111@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alshifa trust eye hospital

Full name of responsible person
Ahmad hasan alizai

Street address
jhelum road

City
rawalpindi

Postal code
42000

Phone
+92 321 5180996

Email
alizai111@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alshifa trust eye hospital
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
Alshifa trust eye hospital
Full name of responsible person
Ahmad hasan alizai
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
jhelum road
City
rawalpindi
Province
punjab
Postal code
42000
Phone
+92 321 5180996
Email
alizai111@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Alshifa trust eye hospital
Full name of responsible person
Ahmad hasan alizai
Position
AP
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
jhelum road
City
rawalpindi
Province
punjab
Postal code
42000
Phone
+92 321 5180996
Email
alizai111@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Alshifa trust eye hospital
Full name of responsible person
Ahmad hasan alizai
Position
AP
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
jhelum road
City
rawalpindi
Province
punjab
Postal code
42000
Phone
+92 321 5180996
Email
alizai111@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
privileged info (by hospital)
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available