Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Randomized Control Trial of Comparing Spironolactone versus Placebo on Sub Retinal Fluid Thickness and Best Correct visual Acuity of Patients with Chronic Central Serous Chorioretinopathy

Protocol summary

Summary

Study will be done in patients with chronic central serous chorioretinopathy from 5 referral hospitals. From these patients who other causes of this clinical feature roll out about them and have symptomatic subretinal fluid (SRF) at least for 3 months and do not like to treat with photodynamic therapy and do not have any contraindications to take Spironolactone will be enrolled. Patients will be randomly divided into two groups that receive drug (spironolactone) or placebo according to block randomization (block sizes are 4 and 6). Sample size is 25 patients in each group . Drug and placebo are definitely the same in the shape, size and pack so the patients and ophthalmologist are blind to intervention. Then patients will take drug or placebo twice a day and will be followed for 3 months and during this period have 3 examinations on 1st and 30th and 90th days. Evaluation will be based on: slit lamp Examination,Optical Coherence Tomography (OCT) imaging, Best Corrected Visual Acuity (BCVA) , on first day, one and three months. Fluorescein angiography on first day, and three months after initiation of treatment. Main outcome measures are subretinal fluid thickness and BCVA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092224140N1**
Registration date: **2015-12-20, 1394/09/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-20, 1394/09/29

Registrant information

Name
Khalil Ghasemi Falavarjani
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Accepted in national network of ophthalmic research.

Expected recruitment start date

2015-10-21, 1394/07/29

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Control Trial of Comparing Spironolactone versus Placebo on Sub Retinal Fluid Thickness and Best Correct visual Acuity of Patients with Chronic Central Serous Chorioretinopathy

Public title

Spironolactone in the treatment of chronic central serous chorioretinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. At least 3 months after CSC (according to OCT without SRF decrease of 10% and symptoms for at least 3 months) (chronic changes:pigmentory changes or central macular edema) 2. Do not take any treatment 3. Subfoveal leak and SRF in macula 4. Do not want to do PDT NO pregnancy and breastfeeding 5. NO any ocular pathology other than refractive disorders 6. NO Addison's disease 7. NO hyperkalemia 8. NO oliguria 9. NO acute renal failure 10. Do not take eplerenone 11. Do not take diuretics 12. Do not taking angiotensin-converting enzyme inhibitors 13. Do not take angiotensin receptor blockers 14. Do not take aldosterone inhibitors comets 15. Do not take NSAIDs 16. Do not take heparin or low molecular weight heparin 17. NO high-potassium diet 18. Do not take exogenous potassium 19. Do not take barbiturates 20. Do not have alcohol Consumption 21. Do not use narcotics 22. Do not take lithium 23. Do not use corticosteroid 24. Do not use ACTH 25. Do not take digoxin 26. Do not have Diabetes 27. Do not have eye surgery in three months 28. No Sensitivity to Fluorescein or Indocyanine 29. No hepatic impairment 30. Do not use of contraception methods in women of childbearing age. 31.In cases where the OCT during the first three months of the SRF is less than 10% of patient Exclusion criteria: 1. If patients do not follow according to protocol. 2.If drug complication appear such as : headache or gastrointestinal symptoms.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Farabi hospital, Tehran University of Medical Sciences.

Street address
Enghelab St., Qazvin Sq., Farabi hospital

City
Tehran

Postal code

Approval date
2015-08-26, 1394/06/04

Ethics committee reference number
IR.TUMS.FARABIH.REC-1394.2

Health conditions studied

1

Description of health condition studied
Chronic Central Serous Chorioretinopathy

ICD-10 code
H35.7

ICD-10 code description
Central serous chorioretinopathy Detachment of retinal pigment epithelium

Primary outcomes

1

Description
Best corrected visual acuity

Timepoint
One month and 3 months after treatment

Method of measurement
By snellen chart

2

Description
Subretinal fluid thickness

Timepoint
One month and 3 months after treatment

Method of measurement
Optical Coherence Tomography (OCT)

Secondary outcomes

empty

Intervention groups

1

Description
Spironolactone , 25mg, BD, for 3 months

Category
Treatment - Drugs

2

Description
Placebo, BD, for 3 months

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi hospital (Tehran University of Medical Sciences)
Full name of responsible person
Dr. Alireza Khodabandeh
Street address
Enghelab St., Qazvin Sq., Farabi hospital
City
Tehran

2

Recruitment center
Name of recruitment center
Torfeh hospital (Shaihd Beheshti University of Medical Sciences)
Full name of responsible person
Dr. Homayoon Nikkhah
Street address
Baharestan St., Baharestan Sq., Torfeh hospital.
City
Tehran

3

Recruitment center
Name of recruitment center
Khatam al anbia hospital (Mashhad University of Medical Sciences)
Full name of responsible person
Dr. Nasser Shoaibi
Street address
Kolahdooz Blvd., Abutaleb Crossroad, Khatam al anbia hospital
City
Mashhad

4

Recruitment center
Name of recruitment center
Labafinejad hospital (Shaihd beheshti University of Medical Sciences)
Full name of responsible person
Dr. Ramin Noorinia
Street address
Boostan 9th St., Pasdaran St., Labafinejad hospital
City
Tehran

5

Recruitment center
Name of recruitment center
Rasoul Akram hospital (Iran University of Medical Sciences)
Full name of responsible person
Dr. Khalil Ghasemi Falavarjani
Street address
Niayesh St., Sattarkhan St., Rasoul Akram hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National network of eye research
Full name of responsible person
Dr. Alireza Lashay
Street address
Enghelab St., Qazvin Sq., Farabi hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National network of eye research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran Eye research center
Full name of responsible person
Dr. Sayyed Amirpooya Alemzadeh
Position
M.D/ Manager
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran university of medical sciences/eye research center

Full name of responsible person
Dr. Khalil Ghasemi Falavarjani

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty