

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

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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: pigmentary 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 (Shahid 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 (Shahid 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

Other areas of specialty/work**Street address**

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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

Position

M.D/ Retinal surgeon

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Position

M.D/ Manager

Other areas of specialty/work**Street address**

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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

Person responsible for updating data

Contact

Name of organization / entity

Eye research center

Full name of responsible person