Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of sprinolactone effect as a treatment for Acute Central Serous Chorio-Retinopathy

Protocol summary

Summary

Objectives: Effect of spironolactone in treatment of acute central serous chorioretinopathy Design: This study is a double blind randomized clinical trial which will be conducted on patients with diagnosis of acute CSCR based on clinical examination and OCT. Setting and conduct: Firstly, Informed consent will be obtained from patients, Later a questionnaire will be completed by researcher and patients will be assigned to placebo and drug groups through random number table. Both groups, 40 patients on the whole, will be treated by a doctor. Inclusion criteria: patients with acute CSCR less than a month Exclusion criteria: patients with history of corticosteroids use; CSCR receiving treatment; other eye diseases; multiple and recurring CSSR; pregnancy; heart disease; kidney disease and hypertension Interventions: Intervention group: Upon diagnosis of CSR, patients will undergo treatment with spironolactone, up to one month. Control group: Upon diagnosis of CSR, patients will undergo placebo treatment, up to one month. Follow up: 15 days, one month Evaluation at each visit: Central macular thickness will be evaluated by OCT and visual acuity and subretinal fluied by Snellen chart If patients respond well to treatment in second visit, drug treatment will continue for another 2 weeks and next visits will be scheduled in 1 month. If no improvement, fluorescein angiography will be performed and the patient will be introduced to medical centers for other treatments such as laser treatments or pdt. Main outcome variables: The volume of fluid under the retina and central macular thickness Visual acuity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051627882N1**
Registration date: **2016-12-12, 1395/09/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-12-12, 1395/09/22

Registrant information

Name
Mohammad Mohsen Keshmirshekan
Name of organization / entity
Shahid Sadoughi University of Medical Sciense
Country
Iran (Islamic Republic of)
Phone
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mkeshmirshekan@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Science

Expected recruitment start date

2015-08-08, 1394/05/17

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of sprinolactone effect as a treatment for Acute Central Serous Chorio-Retinopathy

Public title

Clinical trial to investigate the efficacy of Spironolactone compared with placebo in patients with acute retinal edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients suffering from CSCR in its acute phase (duration of the disease being less than a month). Exclusion criteria : Patients with history of corticosteroids use; CSCR receiving treatment; other eye diseases such as corneal scar, cataract, retinopathy, and etc; multiple and recurring CSSR; pregnancy; heart disease; kidney disease and hypertension

Age

From **19 years** old to **49 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Science

Street address

Shahid Sadoughi University of Medical Science

City

Yazd

Postal code

Approval date

2015-05-16, 1394/02/26

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.226

Health conditions studied

1

Description of health condition studied

Acute Central Serous Chorio-Retinopathy (CSCR)

ICD-10 code

H30.0

ICD-10 code description

Chorioretinal Inflammation H30.0 Focal chorioretinal inflammation Focal: chorioretinitis choroiditis retinitis retinochoroiditis

Primary outcomes

1

Description

The volume of fluid under the retina and macular thickness

Timepoint

Upon entry, two weeks later, a month later.

Method of measurement

OCT

2

Description

visual acuity

Timepoint

Upon entry, two weeks later, a month later.

Method of measurement

Snellen chart

Secondary outcomes

1

Description

drug adverse effect

Timepoint

Upon entry, two weeks later, a month later.

Method of measurement

According to patient's statement

Intervention groups

1

Description

Intervention group: Upon diagnosis of CSR, patients will undergo treatment with 25 mg spironolactone, produced by Minoo Pharmaceutical Company, for four weeks. Patients will be monitored by the researcher in 15 days and 1 month respectively after treatment and the tracked data will be recorded by the researcher. Central macular thickness and sub retinal volume will constantly be evaluated by OCT, and visual acuity will be evaluated as well in each round of visit. If patients respond well to the treatment in second visit (two weeks after the beginning of treatment), the drug treatment will continue for another 2 weeks and next visits will be scheduled in 1 month. In the absence of improvement within 15 days, spironolactone treatment will be suspended and the patient will be re-examined by the doctor after 1 month and if no improvement is seen, fluorescein angiography will be performed and the patient will be introduced to medical centers for other treatments such as laser treatments or pdt.

Category
Treatment - Drugs

2

Description
Control group: Patients in this group will undergo placebo treatment taking one tablet a day for at least one month. Placebo will consist of distilled water and starch in 100 milligrams, with no side effects, and it will be produced by department of pharmacology in Shahid Sadoughi University of Medical Science. Patients with diagnosed CSCR will undergo treatment with placebo for two weeks. Patients will later be investigated by the researcher in 15 days and 1 month respectively after treatment and the tracked data will be recorded by the researcher. In each visit central macular thickness and sub retinal volume, along with visual acuity will be evaluated by OCT. For those patients who respond well to the treatment at the second visit (two weeks after the beginning of treatment) the drug treatment will continue for another 2 weeks in both groups and next visits will be scheduled in 1 month respectively. If no improvement is seen within 15 days, placebo treatment will be suspended and the patient will be re-examined by the doctor after 1 month and if lack of improvement persists, fluorescein angiography will be performed and the patient will later be introduced to medical centers for other treatments such as laser treatments or pdt .

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi University of Medical Science

Full name of responsible person
Mr Mohammad Mohsen Keshmirshekan

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Shahid Sadoughi University of Medical Science

Full name of responsible person
Amir Hushang Mehrparvar

Street address
Shahid Sadoughi University of Medical Science, Shohadaye Gomnam BLVD, yazd, Iran

City
Yazd

Grant name
-

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for research of Shahid Sadoughi University of Medical Science

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
Shahid Sadoughi University of Medical Science

Full name of responsible person
Mr Mohammad Mohsen Keshmirshekan

Position
Ophthalmology Resident

Other areas of specialty/work

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nooshin.yoshany@yahoo.com
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