

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Efficacy and Safety of Crocin Supplementation in Patients With Central SerousChorioretinopathy (CSCR)

Protocol summary

Study aim

To evaluate the efficacy and safety of crocin supplementation in patients with Central serous chorioretinopathy

Design

Two arms parallel-group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

The patients will be enrolled from the ophthalmology retina clinic of Shiraz University of Medical Sciences and randomly allocated to the two study groups with blinding. Two study groups will be followed for 8 weeks and then assessed about outcomes of the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: age of 18-60 years old The diagnosis of CSCR based on clinical and imaging evaluation informed consent Exclusion Criteria: Chronic Central SerousChorioretinopathy Laser treatment (6 months prior to enrollment) Interavital treatment (3 months prior to enrollment)

Intervention groups

Crocin 15 mg/day for 8 weeks Placebo 15 mg/day for 8 weeks

Main outcome variables

1. Best-corrected visual acuity 2. Foveal thickness in optical coherence tomography 3. Subretinal fluid height 4. Subfoveal choroidal thickness 5. Need to Laser Therapy after 2 months 6. Safety and tolerability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110811007297N7**

Registration date: **2021-06-22, 1400/04/01**

Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **0**

Registration date

2021-06-22, 1400/04/01

Registrant information

Name

Mojtaba Heydari

Name of organization / entity

Shiraz university of medical science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-11-30, 1400/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Crocin Supplementation in Patients With Central SerousChorioretinopathy (CSCR)

Public title

Efficacy and Safety of Crocin Supplementation in Patients With Central SerousChorioretinopathy (CSCR)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age of 18-60 years old The diagnosis of CSCR based on clinical and imaging evaluation informed consent

Exclusion criteria:

Chronic Central SerousChorioretinopathy (CSCR) Laser treatment (6 months prior to enrollment) Intravitreal injection (3 months prior to enrollment) Other retinal diseases History of eye diseases Diabetes Mellitus Renal or hepatic diseases Allergy to saffron or crocin Pregnancy or lactation Beta-blocker, diuretic, or corticosteroid (1 week prior to enrollment) Bleeding tendency or any coagulation disorder

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly allocated into two groups, by a secretary instructed to use a block-randomization list. The list will be generated by the computer as a non-stratified list, with the same block lengths.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding of the patients will be achieved by the similarity of drug and placebo. Blinding of the outcome assessor will be achieved by not disclosing patients allocation group to the assessor. Blinding of the statistician will be achieved by not disclosing data groups to him.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand St., infront of Flestin St., Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2021-04-17, 1400/01/28

Ethics committee reference number

IR.SUMS.REC.1400.059

Health conditions studied**1****Description of health condition studied**

Central serous chorioretinopathy

ICD-10 code

H35.71

ICD-10 code description

Central serous chorioretinopathy

Primary outcomes**1****Description**

Best-corrected visual acuity (BCVA)

Timepoint

8 weeks

Method of measurement

Snellen chart

2**Description**

Foveal thickness

Timepoint

8 weeks

Method of measurement

Optical coherence tomography (OCT)

3**Description**

Subretinal fluid height

Timepoint

8 weeks

Method of measurement

Optical coherence tomography (OCT)

4**Description**

subfoveal choroidal thickness

Timepoint

8 weeks

Method of measurement

Optical coherence tomography (OCT)

5

Description

Need to Laser Therapy

Timepoint

8 weeks

Method of measurement

clinical evaluation

6

Description

Safety and tolerability

Timepoint

8 weeks

Method of measurement

based on patients reported adverse events

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Crocin one tablet 15 mg/day before breakfast for 2 months

Category

Treatment - Drugs

2

Description

Control group: Placebo one tablet 15 mg/day before breakfast for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Retina clinic, Shiraz University of Medical Sciences

Full name of responsible person

Mohammadkarim Johari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mojtaba Heydari

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available