Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 imagining evaluation informed consent Exclusion Criteria: Chronic Central SerousChorioretinopathy Laser treatment (6 months prior to enrollment) Interaviteral 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

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Mojtaba Heydari

Name of organization / entity
Shiraz university of medical science

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Iran (Islamic Republic of)

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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 imagining 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
۱۴۳۳۶ - 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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Zand st., infront of Felestin St., Shiraz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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