

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effect of crocin on macular, peripapillary and optic nerve head blood flow in healthy individuals using coherence tomography optical angiography (OCTA)

Protocol summary

Study aim

The goal of this study is to perform a double blinded clinical trial to evaluate the therapeutic effect of crocin on macular, peripapillary and optic nerve head blood flow.

Design

This is a double blinded randomized clinical trial with two-arm parallel group. The crocin and placebo tablets are made in similar shape, color, and size. The macular, peripapillary and optic nerve head blood flow will be determined before and two hours after taking two tablets of crocin or placebo.

Settings and conduct

Study will be done in Khatam-al-Anbia Hospital under the supervision of specialist. Tablets will be prepared from pure crocin in Mashhad Pharmacy School. In this double blinded trial physician, participants and researchers will not aware of the pill contents. After selecting the participants they will be randomly divided into crocin or placebo groups. The macular, peripapillary and optic nerve head blood flow will be determined before and two hours after taking two tablets of crocin or placebo.

Participants/Inclusion and exclusion criteria

The age between 20 and 50
Lack of systemic disease such as diabetes and hypertension
Not using systemic drugs
Lack of any intraocular pathology
No history of eye surgery

Intervention groups

Healthy people who their retinal blood flow are examined before and 2 hours after receiving two crocin tablets (15 mg).
Placebo group: Healthy people who their retinal blood flow are examined before and two hours after receiving two placebo tablets.

Main outcome variables

Macular blood flow
Peripapillary blood flow
Optic nerve head blood flow

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130418013058N15**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Seyed Ahmad Mohajeri

Name of organization / entity

Pharmaceutical Research Center, School Of Pharmacy, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of crocin on macular, peripapillary and optic nerve head blood flow in healthy individuals using coherence tomography optical angiography (OCTA)

Public title

The effect of crocin on retinal arteries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The age of the volunteer should be between 20 and 50
Lack of systemic disease such as diabetes and hypertension
Do not use systemic drugs
Lack of any intraocular pathology
No history of eye surgery

Exclusion criteria:

Any eye disease
Age less than 20 or more than 50
History of eye surgery

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

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

four-digit numbers, obtained from "random number table", will be applied for coding of tablet containers and randomization. First column of the random number table will be assigned to crocin group and the second one to placebo. The codes will be written on a piece of paper and put into an opaque envelope. The envelopes will be sealed and placed sequentially in a box and kept by researcher and physician. Envelopes and their code will be assigned sequentially to eligible participants in order of their arrival time.

Blinding (investigator's opinion)

Double blinded

Blinding description

Crocine and placebo tablets will be prepared in a similar shape, color, and size, stored in a dark container and coded by a pharmacist. The physician, researcher, and participants will not be aware of the content of the pills inside the container.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

School of Pharmacy, Ferdowsi University complex, Azadi square, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-05-01, 1399/02/12

Ethics committee reference number

IR.MUMS.REC.1399.212

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

The blood flow of the macula, peripapillary and head of optic nerve

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Macular blood flow

Timepoint

Before the intervention and two hours after taking 2 tablets of 15 mg crocin or placebo

Method of measurement

Coherence Optical Tomography Angiography (OCTA)

Secondary outcomes**1****Description**

blood flow of peripapillary and optic nerve head

Timepoint

Before the intervention and two hours after taking two tablets of crocin or placebo

Method of measurement

Coherence Optical Tomography Angiography (OCTA)

Intervention groups

1

Description

Intervention group: Two crocin tablets (15 mg) will be given into healthy participants in the project. Optical coherence tomography (OCT) imaging with angiography will be done before and after two hours of crocin administration.

Category

Treatment - Drugs

2

Description

Control group: Two placebo tablets will be given into healthy participants in the project. Optical coherence tomography (OCT) imaging with angiography will be done before and after two hours of placebo administration, .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-Anbia Hospital

Full name of responsible person

Seyed Ahmad Mohajeri

Street address

Khatam-al-Anbia Hospital, Gharani Boulevard, Mashhad

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mohajeriam@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah street, Mashhad University of Medical Sciences

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vresearch@mums.ac.ir

Grant name

Grant code / Reference number

980883

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Mohajeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Primary and secondary outcome data and demographic data

When the data will become available and for how long

6 months after publication of the results

To whom data/document is available

Researchers and who works in pharmaceutical industries

Under which criteria data/document could be used

Analysis and interpretation of data is allowed.

From where data/document is obtainable

Dr. Seyed Ahmad Mohajeri, email: mohajeriam@mums.ac.ir, tel: 098-51-31801181

What processes are involved for a request to access data/document

The data request must be sent by email and the documents of the applicant must be attached. If approved the data will be sent within a month.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Mohajeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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