

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Crocin on macular and optic nerve head vascular density in non-proliferative diabetic retinopathy patient with non-central macular involvement

Protocol summary

Study aim

Design

Settings and conduct

Participants/Inclusion and exclusion criteria

Intervention groups

Main outcome variables

2021-03-17, 1399/12/27

Expected recruitment end date

2021-04-16, 1400/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210310050669N1**

Registration date: **2021-03-14, 1399/12/24**

Registration timing: **prospective**

Last update: **2021-03-14, 1399/12/24**

Update count: **0**

Registration date

2021-03-14, 1399/12/24

Registrant information

Name

Ali Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3728 1401

Email address

eslamia961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

Scientific title

Effect of Crocin on macular and optic nerve head vascular density in non-proliferative diabetic retinopathy patient with non-central macular involvement

Public title

Effect of Crocin on macular and optic nerve head vascular density in non-proliferative diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (18 years and older) with type 2 diabetes without central involvement macular edema according to ETDRS criteria (early treatment diabetic retinopathy study) in the studied eye Best corrective visual acuity equal or upper than 7/10 (20/30) according to Snellen chart HbA1c has been 6.5-9.5 during the last 3 months No need for standard treatment including Injection, Macula Laser or Retina Laser The absence of other serious illnesses, such as liver and kidney failure The maximum severity of diabetic retinopathy be non-proliferative Controlled blood pressure or lipid profile in hypertension and hyperlipidemia patients if present

Exclusion criteria:

The presence of other ophthalmic diseases that effects macular edema (like Retinal vein occlusion, uveitis, Epiretinal membrane) Patients with anterior segmentation of the eye disorders (Cornea, anterior chamber, Iris, and lens) History of any intraocular

surgery except cataract surgery (more than 6 months before entrance study) Sub foveal hard exudates deposition Pregnancy, Breast feeding Need for Standard treatment including Injection, Macula Laser, or Retina Laser Allergy to saffron The presence of other ophthalmic diseases that effects vision (glaucoma, vascular obstruction, macular pathology)

Age

From **18 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: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization For each tablet container, four-digit codes will be randomly labeled to each box by pharmacist . The therapist will give it to the patient randomly without knowledge of the type of medicine. Thus, the nature of each code will be unclear until the analysis of the results.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Crocin and placebo tablets will be prepared in a similar shape, color, and size, stored in a dark container and coded by a pharmacist. The treating physician, researcher, and patients will not be aware of the code printed on the container.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee School of Medicine-
Mashhad University of Medical Sciences

Street address

Khatam Ol-Anbia Eye Hospital, Abutaleb Junction,
Ghareni blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9178865898

Approval date

2021-02-23, 1399/12/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.804

Health conditions studied

1

Description of health condition studied

Diabetic Retinopathy

ICD-10 code

E11.3

ICD-10 code description

Type 2 diabetes mellitus with ophthalmic complications

Primary outcomes

1

Description

Macular and optic nerve head vascular density

Timepoint

Before intervention, and 3 months later

Method of measurement

Optovue Optical Coherence Tomography (OCT)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving one tablet of Crocin (15 mg)daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: Receiving one tablet of placebo daily for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Ol-Anbia Eye Hospital

Full name of responsible person

Dr. Ali Eslami

Street address

Khatam Ol-Anbia Eye Hospital, Abutaleb Junction,
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Email

eslamia961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Between shahis Javan and Shahid Al-Shahidi, Shahid
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vresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Dr. Ali Eslami

Position

Resident of ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Maryam Hosseini

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not 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