

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)		Mashhad
Age		Province
From 18 years old		Razavi Khorasan
Gender		Postal code
Both		9178865898
Phase		Approval date
2-3		2021-02-23, 1399/12/05
Groups that have been masked		Ethics committee reference number
- Participant - Care provider - Investigator - Outcome assessor - Data analyser		IR.MUMS.MEDICAL.REC.1399.804
Sample size		Health conditions studied
Target sample size: 24		<u>1</u>
Randomization (investigator's opinion)		Description of health condition studied
Randomized		Diabetic Retinopathy
Randomization description		ICD-10 code
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.		E11.3
Blinding (investigator's opinion)		ICD-10 code description
Triple blinded		Type 2 diabetes mellitus with ophthalmic complications
Blinding description		Primary outcomes
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.		<u>1</u>
Placebo		Description
Used		Macular and optic nerve head vascular density
Assignment		Timepoint
Parallel		Before intervention, and 3 months later
Other design features		Method of measurement
		Optovue Optical Coherence Tomography (OCT)
Secondary Ids		Secondary outcomes
empty		empty
Ethics committees		Intervention groups
<u>1</u>		<u>1</u>
Ethics committee		Description
Name of ethics committee		Intervention group: Receiving one tablet of Crocin (15 mg)daily for 3 months
Research ethics committee School of Medicine- Mashhad University of Medical Sciences		Category
Street address		Treatment - Drugs
Khatam Ol-Anbia Eye Hospital, Abutaleb Junction, Ghareni blvd		<u>2</u>
City		Description
		Control group: Receiving one tablet of placebo daily for three months
		Category
		Treatment - Drugs
		Recruitment centers
		<u>1</u>
		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,
Ghareni blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

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
Fakori Blvd., Mashhad.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3841 1538

Email

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Fax

Email

eslamia961@mums.ac.ir

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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Email

hoseinimm@mums.ac.ir

Person responsible for updating data

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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Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 1401

Fax

Email

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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