

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Monotherapy effect of Crocin on mild to moderate maculopathy; a clinical trial study

Protocol summary

Study aim

the aim of this Double blind Clinical Trial is
Determination of the Monotherapy Therapeutic Effects of
Crocin on Patients with Maculopathy

Design

In this double blind randomized trial with two arm
parallel group, the Crocin and Placebo Tablets are made
in completely similar shape, color, and size

Settings and conduct

Study will be conducted in Khatam-al-Anbia Hospital
under the supervision of specialized doctors, Tablets will
be produced from pure Crocin at Mashhad Pharmacy
School. In this trial, physician, researcher, patient, and
the test analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with mild to moderate
Maculopathy that center has not been involved, Best
corrected visual acuity equal or upper than 8/10
according to Snellen chart, Diabetes mellitus with HbA1c
5.8-7 during last 3 months, No need for standard
treatment including Injection, The ability to understand
the study, The Maximum Severity of DR be non-
Proliferative Step, Blood Pressure is controlled.

Intervention groups

Treatment group 1: patients with Diabetic Maculopathy
that used (15 mg per day) of crocin Tablet for 3 months.
Crocin is a herbal product and an active constitute of
saffron. Placebo group: patients with Diabetic
Maculopathy that used one Placebo Tablet per day for 3
months.

Main outcome variables

Macular Thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130418013058N13**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

Registration date

2019-07-30, 1398/05/08

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)

Phone

+98 51 1882 3255

Email address

mohajeria@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-31, 1397/10/10

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Monotherapy effect of Crocin on mild to moderate
maculopathy; a clinical trial study

Public title

Effect of Crocin on mild to moderate maculopathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with mild to moderate Maculopathy that center has not been involved Best corrective visual acuity equal or upper than 8/10 according to Snellen chart Diabetes mellitus with HbA1c 5.8-7 during 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 ability to understand the study, interventions and possible complications The Maximum Severity of Diabetic Retinopathy be non-Proliferative Step Blood Pressure is controlled
Exclusion criteria:
 The presence of other ophthalmic conditions Another eye disease that can affect macular edema (Retinal vein occlusion, uveitis) Patients with anterior segmentation of the eye disorders History of vitrectomy surgery The presence of subfoveal hard exudates deposition History of intraocular surgery in the last 3 months

Age
From **18 years** old to **80 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
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)
Double 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

Ethics committee of Mashhad University of Medical Science

Street address

Deputy of Science and Technology, Mashhad University of Medical Sciences, next to the Hoveizeh cinema, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.MUMS.REC.1397.207

Health conditions studied

1

Description of health condition studied

Diabetic Retinopathy

ICD-10 code

*H36.0

ICD-10 code description

Diabetic Retinopathy

Primary outcomes

1

Description

Central Macular Thickness

Timepoint

Before Intervention, and After Three Months

Method of measurement

Spectralis OCT Device

Secondary outcomes

1

Description

FBS Level

Timepoint

Before intervention, and three months later

Method of measurement

FBS Level Test

Intervention groups

1

Description

Intervention group: Receiving One Tablet of Crocin (15 mg) daily for three 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-al-Anbia Hospital

Full name of responsible person

Dr. Seyedeh Maryam Hosseini

Street address

Abotaleb Intersection toward Ferdosi Square, Mashhad-Iran

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9195965919

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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.

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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

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. Seyed Ahmad Mohajeri

Position

PhD in Pharmacology, Faculty Member of Pharmacodynamics and Toxicology, School of Pharmacy and Targete

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

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PhD in Pharmacology, Faculty Member of Pharmacodynamics and Toxicology, School of Pharmacy and Targete

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Latest degree

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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

No - There is not 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