

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Study of the effect of Crocin on patient with open angle glaucoma by double blinded, randomized and placebo-controlled clinical trial

Protocol summary

Summary

The aim of this study was to investigate the effect of crocin as an effective anti-inflammatory and anti-oxidant saffron agent in preventing possible damage to neurons and retinal tubules and consequent irreversible blindness in glaucoma. In this double blind clinical trial, the sample size was taken using the Sigma Plot software. 40 patients with open angle glaucoma who have an upper IOP of 21 and no history of surgery and divided into two groups of 20, one in the intervention group of crocin 15 mg and the other in the placebo group. For uniformity and double blind of the study, placebo tablets are in the same size and shape as the crocin tablets. The internal pressure of the eye, the nerve fibers of the patient's nerve before the intervention, the end of the two months and the end of the 4 months in both groups are examined. Also, the possible side effects of crocin in this trial will be questioned by each patient. It is hoped that the crocin tablet can be used as a supplement in the future as a routine for the treatment of open angle glaucoma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030113058N6**

Registration date: **2017-09-17, 1396/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

Name

Seyed Ahmad Mohajeri

Name of organization / entity

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

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Science

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Crocin on patient with open angle glaucoma by double blinded, randomized and placebo-controlled clinical trial

Public title

Effect of Crocin on patient with open angle glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients (40 years and older) with open angle glaucoma; The ability to understand the generalities of study, Interventions and possible complications; Eye pressure (IOP) above 21 with or without treatment; cup-to-disc ratio $\geq 0.4 > 0.8$; Similarity of glaucoma intensity in two eyes. Exclusion criteria: The presence of eye disease and the use of steroids that can

affect eye pressure; History of intraocular surgery and laser therapy; Pregnancy and breastfeeding; Saffron sensitivity; Advanced glaucoma at the bedside, based on prime criteria (It is done for all patients with glaucoma routinely).

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MUMS.SP.1395.70

Health conditions studied

1

Description of health condition studied

Primary open-angle glaucoma

ICD-10 code

H40.1

ICD-10 code description

Primary open-angle glaucoma

Primary outcomes

1

Description

Intraocular Pressure

Timepoint

Two months before and two months after treatments

Method of measurement

Tonometer

2

Description

Retinal nerve fiber layer

Timepoint

Before the intervention and at the end of month 2 and 4 months later

Method of measurement

RNFL OCT

Secondary outcomes

1

Description

Side effects of crocin

Timepoint

Before intervention, and two and four months later

Method of measurement

Questionnaire for side effect of crocin

Intervention groups

1

Description

Treatment Group: Patients with open angle glaucoma that used 15 mg per day of crocin tablet with the routine treatment of open-angle glaucoma drug. Crocin is a full herbal medicine constitute of saffron.

Category

Treatment - Drugs

2

Description

Control group: Patients with open angle glaucoma that used one placebo tablet per day with routine drugs of glaucoma.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-Al-Anbia Hospital

Full name of responsible person

Dr. Saeed Shokouhi

Street address

Abotaleb Intersection toward Ferdosi Square.

City

Mashhad

mohajerija@mums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyed Ahmad Mohajeri, Dr. Mohsen Tafaghodi

Street address

Shahid Fakori Blvd., Between shahis Javan and Shahid Al-Shahidi, Mashhad

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Other areas of specialty/work**Street address**

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

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Full name of responsible person

Samaneh Sepahi

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty