Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Oct 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.t 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 ≥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
Mashahd

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

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
Mashahad
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
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Position
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Person responsible for updating data

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Samaneh Sepahi
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00
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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