Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Crocin on Diabetic Retinopathy and Cataract; A Double Blind Placebo Controlled Randomized Clinical Trial

Protocol summary

Summary

Diabetic retinopathy is one of the most eye complications in diabetic patients. Studies have shown that saffron extract contains numerous compounds, including crocin, which is the main active ingredient in saffron and is mostly observed as crocetin glycosides. Due to anti-inflammatory and antioxidant properties, crocin can be used in the treatment and prevention of diabetic maculopathy, cataract and eye diseases, which inflammatory and oxidative mechanisms are involved in their pathogenesis. In this study, 60 patients with diabetic maculopathy were studied in 3 groups. These groups included patients with 5 mg per day of crocin, patients with 15 mg per day of crocin and patients with placebo, respectively. Patients initially undergo a complete ophthalmic examination and the central macular thickness is measured using OCT spectralis. Immediately after three months of crocin prescription, the patients undergo a complete ophthalmic examination and OCT. Data obtained before and after treatment are compared, as well the results are compared with the control group. According to the specialist as well as for the healing integration process, patients whom their central macular thickness is close to each other's will be selected in the placebo and treated groups. Also, they are under the same standard treatment (laser or Austin or steroids). Therefore, the results will be reliable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062113058N2**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Crocin on Diabetic Retinopathy and Cataract; A Double Blind Placebo Controlled Randomized Clinical Trial

Public title

Effects of Crocin on Diabetic Retinopathy and Cataract

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult patients (18 ≤) with type 1 and 2 diabetes and CSME (clinically significant macular edema) according to ETDRS criteria (early treatment diabetic retinopathy study) in the studied eye, or patients who are diagnosed with cataract as well as central macular thickness in OCT above 296 microns, well controlled diabetes mellitus (HbA1c less than or equal to 8.5 over the last 3 months), and the ability to understand overview of the study, treatment and possible side effects. For cataract patients:Patients who are scheduled to undergo cataract surgery in the next 3 months and are not in a state of emergency. Grading based on a 0 to 4, according to criteria:0 = lens normal, clear, 1 = lens shows a slight blur, 2 = lens represents darkness average, 3 = lens represents the darkness of and the details are, 4 = Lens indicator cataract is done Exclusion criteria: 1. Presence of other eye abnormalities (non-retina causes, etc.) that despite an improvement in macular edema, do not improve visual acuity. 2. Other eye diseases (retinal vein occlusion, uveitis, retinal epithelial membrane) that can affect macular edema. 3. Patients with anterior segment abnormalities of the eye (cornea, anterior chamber, iris, or lens) 4. History of vitrectomy 5. Subfoveal hard exudates deposition 6. Existence treatment required PDR 7. Intraocular surgery within the last 3 months 8. Pregnancy 9. Vitreous hemorrhage

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study of patients in the treatment groups and the placebo group are randomly assigned . Doctors have no information of intervention .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
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
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Approval date
2014-12-10, 1393/09/19

Ethics committee reference number
research/930361/1/1205

Health conditions studied

1

Description of health condition studied
Diabetic Retinophaty

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

2

Description
Measure The Opacity Of The Lens

Timepoint
At The Time Of The Visit And Once After Of The End Of Treatment Period

Method of measurement
Microscopes Equipped With Digital Cameras And Upper Ring Light

Secondary outcomes

1

Description
side effects of crocin

Timepoint
Before intervention,and three months later

Method of measurement
Questionnaire for side effect of crocin

Intervention groups

1

Description
Group 1:Included Patients With 5 mg per Day Of Crocin.
Category
Treatment - Drugs

2

Description
Intervention Group 2: Patients With 15 mg per Day Of Crocin.
Category
Treatment - Drugs

3

Description
DiabeticPpatients With Placebo For 3 Months Treatments.
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
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Abotaleb Intersection toward Ferdosi Square, Mashhad-Iran
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences
Full name of responsible person
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Mashahad
Grant name
مشارکت 80 درصدی اعتبار پژوهشی مجری طرف قرارداد و 20. درصدی اعتبار مرکز تحقیقات داورسانی هدفمند
Grant code / Reference number
930361
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

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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