Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Pilot Study on the effectiveness of crocin as a drug supplement in the treatment of ocular complications of Behcet's disease; a clinical trial

Protocol summary

Study aim
Study is a double blind clinical trial for determination of the therapeutic effects of Crocin on patients with Behcet's disease.

Design
In this double blind randomized trial with two arm parallel group, the crocin and placebo tablets were made in completely similar shape, color, and size

Settings and conduct
This study will be conducted in Ḵhatam-al-Anbia hospital with ophthalmologist, also tablets will be produced from pure crocin at Mashhad Pharmacy School. In this double-blind trial, physician, researcher and patient will not be aware of distribution of tablets in crocin and control groups.

Participants/Inclusion and exclusion criteria
Including Criteria: A patient with Active Behcet's with ocular complications is selected according to the sun criteria, Patients with Behcet's syndrome with anterior, posterior, or diffuse eye involvement, Long-term illness of the eye with active retinal vasculitis and macular edema, Age over 18 years of both sexes A patient with Behcet's who is resistant (without improvement or exacerbation of the eye disease) or an approximate response (mild to moderate) to Combination therapy (Psychosis and Steroids drugs), The ability to understand the overall study. Exclusion Criteria: Patients with bilateral vision loss, Patients receiving anti-TNF drugs such as thalidomide in the past three months, Patients with a history of Weak immune system, Severe viral infections including hepatitis, pneumoniain the last three months, Pregnancy and breastfeeding, Sensitivity to saffron, alcohol consumption, Cataract and other general items, Diabetes

Intervention groups
Treatment group: patients with Behçet's disease that receive 15 mg/day of crocin tablet for 3 months. Placebo group : patients with Behçet's disease that receive one Placebo tablet per day for 3 months.

Main outcome variables
Assessing the Rate of Ocular inflammation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130418013058N12**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

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

Expected recruitment start date
2019-02-19, 1397/11/30
Expected recruitment end date
2020-02-19, 1398/11/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Pilot Study on the effectiveness of crocin as a drug supplement in the treatment of ocular complications of Behcet's disease; a clinical trial

Public title
Effect of crocin on ocular complications of Behcet's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A patient with active Behcet's with ocular complications is selected according to the sun criteria, Patients with Behcet's syndrome with anterior, posterior, or diffuse eye involvement Long-term illness of the eye with active retinal vasculitis and macular edema Age over 18 years of both sexes A patient with Behcet's who is resistant (without improvement or exacerbation of the eye disease) or an approximate response (mild to moderate) to combination therapy (Psychosis and Steroids drugs) The ability to understand the overall study, interventions and possible complications
Exclusion criteria:
Patients with bilateral vision loss Patients receiving anti-TNF drugs such as thalidomide and pentoxifylline in the past three months. Patients with a history of immunosuppression include a viral infection such as tuberculosis Severe viral infections including hepatitis, pneumonia, pyelonephritis, or hepatitis in the last three months Pregnancy and breastfeeding Sensitivity to saffron alcohol consumption Cataract and other general items Diabetes
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
- Data and Safety Monitoring Board

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 not be known 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 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
2018-10-20, 1397/07/28
Ethics committee reference number
IR.MUMS.REC.1397.245

Health conditions studied

1

Description of health condition studied
Behcet's Disease
ICD-10 code
M35.2
ICD-10 code description
Behcet's disease

Primary outcomes

1

Description
Ocular Inflammation
Timepoint
Before Intervention, and after three months
Method of measurement

Fluorescein Angiography

Secondary outcomes

1

Description
Best Corrected Visual Acuity
Timepoint
Before Intervention, and After Three Months
Method of measurement
Snellen Chart

Intervention groups

1

Description
Intervention group: Receiving one tablet of Crocin (15 mg) for three months
Category
Treatment - Drugs

2

Description
Control group: Receiving one tablet of placebo 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 Ferdwosi Square, Mashhad-Iran
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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?
No
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
Associate professor, PhD in Pharmacology, Faculty Member of Pharmacodynamy and Toxicology, School of
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
As regards to that the work has not begun, a definitive decision on this information has not yet been taken.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available