

# 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 Khatam-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, pneumonia in the last three months, Pregnancy and breastfeeding, Sensitivity to saffron, alcohol consumption, Cataract and other general items, Diabetes

##### Intervention groups

Treatment group: patients with Behcet's disease that receive 15 mg/day of crocin tablet for 3 months. Placebo group : patients with Behcet'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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1882 3255

##### Email address

mohajerija@mums.ac.ir

##### 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9195965919

##### Phone

+98 51 3728 1401

##### Email

KH.PR@mums.ac.ir

## 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

#### City

Mashahd

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Phone

+98 51 3841 1538

#### Email

vresearch@mums.ac.ir

#### 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 Pharmacodynamics and Toxicology, School  
of

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

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

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##### Postal code

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##### Email

mohajeriam@mums.ac.ir

## Person responsible for scientific 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 Pharmacodynamics and Toxicology, School  
of

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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Mashhad University of Medical Sciences

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Dr. Seyed Ahmad Mohajeri

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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