

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of crocin on inflammation factors, DNA damage and biomarkers of oxidative injury in the blood of patients with multiple sclerosis

#### Protocol summary

##### Summary

The purpose of this study is evaluation the effect of crocin on inflammatory markers, oxidative damage and DNA damage in the blood of people with multiple sclerosis. Multiple sclerosis is an autoimmune disease in which the immune system attacks the nerve cells that result in nerve demyelination cause neurological disorder. Oxidative stress, free radicals and neuritis have an important role in pathogenesis of the disease. In this study that is done randomly on 40 outpatients in Farshchian hospital of Hamedan. The outpatients divide into 2 groups; the drug group and Placebo group. In the drug group patients will receive two crocin capsules per day for 28 days. The control group will receive two placebo per day, too. After one month of intervention we will measure thiol groups lipid peroxidation, total antioxidant capacity, DNA damage, IL-17, TNF-a in serum of MS patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092713194N2**

Registration date: **2017-04-30, 1396/02/10**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-30, 1396/02/10

##### Registrant information

###### Name

Akram Ranjbar

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0031

###### Email address

a.ranjbar@umsha.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

###### Expected recruitment start date

2017-05-05, 1396/02/15

###### Expected recruitment end date

2017-07-14, 1396/04/23

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of crocin on inflammation factors, DNA damage and biomarkers of oxidative injury in the blood of patients with multiple sclerosis

###### Public title

The effect of crocin on MS

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

inclusion criteria: Recently diagnosed relapsing-remitting MS patients; Patients between 20-40 years old exclusion criteria: Receiving immunomodulatory drugs such as interferons; Diabetes; Chronic disease like cardiac, liver or kidney disease; Smoking; Pregnancy and lactation; EDSS>4; Any rheumatologic disease or vasculitis; History of hypersensitivity to saffron

###### Age

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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 Hamedan University of Medical Sciences

**Street address**

Hamedan, Pazhoohesh Crossroad, In front of the Luna park, Hamedan University of Medical Sciences

**City**

Hamedan

**Postal code****Approval date**

2016-08-18, 1395/05/28

**Ethics committee reference number**

IR.UMSHA.REC.1395.246

**Health conditions studied****1****Description of health condition studied**

Multiple sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis (of): NOS brain stem cord disseminated generalized

**Primary outcomes****1****Description**

IL-17

**Timepoint**

first week and fourth week

**Method of measurement**

ELISA

**2****Description**

TNF-a

**Timepoint**

first week and fourth week

**Method of measurement**

ELISA

**3****Description**

DNA damage

**Timepoint**

first week and fourth week

**Method of measurement**

ELISA

**4****Description**

Lipid peroxidation

**Timepoint**

first week and fourth week

**Method of measurement**

ELISA

**5****Description**

Total antioxidant capacity

**Timepoint**

first week and fourth week

**Method of measurement**

spectrophotometry

**6****Description**

Thiol groups

**Timepoint**

first week and fourth week

**Method of measurement**

Spectrophotometry

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients receiving 30 mg of crocin twice daily.

**Category**

Treatment - Drugs

## 2

### Description

Control group: patients receiving placebo twice daily.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshchian Hospital of Hamedan

##### Full name of responsible person

Masoud Ghiasian

##### Street address

Farshchian hospital, Pastor crossroad, Hamedan

##### City

Hamedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Saeed Bashirian

##### Street address

In front of Luna park, Hamadan

##### City

Hamedan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Akram Ranjbar

##### Position

Associate professor/PhD of toxicology

#### Other areas of specialty/work

#### Street address

In front of Luna park, Hamedan

#### City

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#### Postal code

#### Phone

+98 81 3838 1591

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Akranjbar2015@gmail.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Akram Ranjbar

##### Position

Associate Professor/ PhD of Toxicology

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Forugh Khamisabadi

##### Position

Pharmacy student

##### Other areas of specialty/work

##### Street address

Tehran, 17 Shahrivar street, Number18

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1371958444

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##### Email

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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*