# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of crocin on biomarkers of oxidative stress in the Saliva and Urine of patients with multiple sclerosis

## Protocol summary

**Summary**

This study aimed to determine the effect of crocin saffron on biomarkers of oxidative stress in the saliva and urine of patients with multiple sclerosis. The study was a randomized controlled trial study design. The inclusion criteria contains recently diagnosed relapsing-remitting MS patients and aged between 20 and 40 years. Exclusion criteria contains history of hypersensitivity to saffron, diabetes, underlying chronic illnesses including liver disease, kidney, lung and heart, smoking, pregnancy and lactation, any rheumatologic disease or vasculitis. In this study, 40 patients referred to the Farshchian hospital of Hamedan (in succession), were randomly assigned to the intervention and placebo groups with respect concealment of allocation will be allocated. Intervention group consume 30 mg capsule of crocin per day (15 mg twice daily) and placebo groups (two capsules per day) for 15 days. In this study, catalase enzyme, total antioxidant capacity of saliva, Thiol groups of saliva, lipid peroxidation, total antioxidant capacity of urine, Thiol levels of urine, before the study and at the end of the treatment period, is measured.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016122013194N3**
Registration date: **2017-03-05, 1395/12/15**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-03-05, 1395/12/15

**Registrant information**

**Name**

Akram Ranjbar

**Name of organization / entity**

Hamedan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Not yet recruiting**

**Funding source**

Vice chancellor for research, Hamedan university of medical sciences

**Expected recruitment start date**

2051-03-20, 1429/12/29

**Expected recruitment end date**

2071-03-20, 1449/12/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of crocin on biomarkers of oxidative stress in the Saliva and Urine of patients with multiple sclerosis

**Public title**

The effect of crocin in multiple sclerosis patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria:Recently diagnosed relapsing-remitting MS patients; Patients between 20-40 years old exclusion criteria: Receiving corticosteroids before the study; Receiving immunomodulatory drugs such as interferons before the study; Diabetes; Underlying chronic illnesses including liver disease, kidney, lung and heart; Smoking;

Pregnancy and lactation; Any rheumatologic disease or vasculitis; History of hypersensitivity to saffron

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

**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)**
Single blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
ethic Committee of hamedan university of medical sciences

**Street address**
hamedan university of medical sciences

**City**
hamedan

**Postal code**

**Approval date**
2016-11-19, 1395/08/29

**Ethics committee reference number**
IR.UMSHA.REC.1395.375

### 2

**Ethics committee**

**Name of ethics committee**
Hamedan University Research Ethics Committee of Medical Sciences

**Street address**
Hamedan University of Medical Sciences

**City**
Hamedan

**Postal code**

**Approval date**
2016-10-29, 1395/08/08

**Ethics committee reference number**
IR.UMSHA.REC.1395.349

## Health conditions studied

### 1

**Description of health condition studied**
Multiple sclerosis

**ICD-10 code**
G36

**ICD-10 code description**
Other acute disseminated demyelination

### 2

**Description of health condition studied**
Multiple sclerosis

**ICD-10 code**
G35

**ICD-10 code description**
Multiple sclerosis

### 3

**Description of health condition studied**
Multiple sclerosis

**ICD-10 code**
G37

**ICD-10 code description**
Other demyelinating diseases of central nervous system

## Primary outcomes

### 1

**Description**
Total antioxidant capacity of urine

**Timepoint**
Before and after intervention

**Method of measurement**
spectrophotometer TPTZ reagent in a 593 nm

### 2

**Description**
Catalase Enzyme

**Timepoint**
Before and after intervention

**Method of measurement**
According U / ml using Spectrophotometry

### 3

**Description**
Total antioxidant capacity of saliva

**Timepoint**
Before and after intervention

**Method of measurement**
According U / ml using Spectrophotometry

### 4

**Description**
Thiol groups of saliva

**Timepoint**

Before and after intervention

**Method of measurement**

According U / ml using Spectrophotometry

**5**

**Description**

Lipid peroxidation

**Timepoint**

Before and after intervention

**Method of measurement**

spectrophotometer TBA reagent in a 532 nm

**6**

**Description**

Thiol levels in urine

**Timepoint**

Before and after intervention

**Method of measurement**

HU method

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

In the control group a placebo (a capsule that is not crocin of saffron, but the patients are not told anything about it) two capsules a day for 15 days to receive oraly.

**Category**

Placebo

**2**

**Description**

In the intervention group crocin saffron capsules of 30 mg per day (15 mg twice daily) given for 15 days.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Farshchian Hospital

**Full name of responsible person**

Dr. Masoud Ghiasian

**Street address**

Farshchian Hospital

**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**

Hamedan University of Medical Sciences

**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**

Dr. Akram Ranjbar

**Position**

PhD in Toxicology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*