Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

+98 81 1838 0031

Email address

a.ranjbar@umsha.ac.ir

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

Street address

Hamedan University of Medical Sciences

City

Hamedan

Postal code

Phone

00

Fax

Email

Akranjbar1389@yahoo.com

Web page address

Person responsible for scientific 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
Street address
Hamedan University of Medical Sciences
City
Hamedan
Postal code
Phone
00
Fax
Email
Akranjbar1389@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Hamedan University of Medical Sciences
City
Hamedan
Postal code
Phone
00
Fax
Email
Akranjbar1389@yahoo.com
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