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 devide 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

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Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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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 commitee 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
spectrophotometery

6

Description
Thiol groups
Timepoint
first week and fourth week
Method of measurement
Spectrophotometery

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 placebotwice daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hosptal 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
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Person responsible for updating data

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Forugh Khamisabadi
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Pharmacy student
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Tehran, 17 Shahrivar street, Number18
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F.Khamisabadi1371@gmail.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