Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigate the effect of Crocin on Cognitive impairment, mental health,Oxidative Stress and inflammatory factors in Multiple Sclerosis patients

Protocol summary

Study aim

1.Determining the frequency of cognitive disorders in the study population in the group of Crocin and Placebo 2.Comparison of changes in cognitive impairment before and after drug administration between Placebo and Crocin 3.Determining the frequency of depression and anxiety in the study population in the group of Crocin and Placebo 4.Comparison of changes in depression and anxiety before and after drug administration between Placebo and Crocin

Design

Clinical trial with control group, parallel groups, double-blind (both patients and researchers), randomized, 50 patients, phase 2

Settings and conduct

Population and sample size: 50 eligible multiple sclerosis patients and referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. Time of intervention: 8 weeks.

Participants/Inclusion and exclusion criteria

Entry requirements; Age between 18 and 55 years; Testable measurable cognitive impairment McFims attributed to multiple sclerosis;Testable Measurable mental health impairment including anxiety and depression (Beck) attributed to Multiple Sclerosis; Diagnosis of multiple sclerosis based on McDonald's criteria. No entry conditions; sensitivity to crocin products; Clinical relapse of Multiple Sclerosis with in 30 days of screening

Intervention groups

Group A will be treated with Crocin and group B will be treated with Placebo

Main outcome variables

Language; executive function; processing speed ; functional memory; new learning power ; depression ; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054087N1**
Registration date: **2022-03-09, 1400/12/18**
Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**
Update count: **0**

Registration date

2022-03-09, 1400/12/18

Registrant information

Name

Bahador Rezapoor kafteroodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5533 3780

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-08, 1401/01/19

Expected recruitment end date

2022-05-09, 1401/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of Crocin on Cognitive impairment, mental health,Oxidative Stress and inflammatory factors in Multiple Sclerosis patients

Public title

Investigate the effect of Crocin in Multiple Sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Multiple Sclerosis based on McDonald's criteria Age between 18 to 55 years Testable Measurable Cognitive impairment (MACFIMS) attributed to Multiple Sclerosis Testable Measurable mental health impairment including anxiety and depression (Beck) attributed to Multiple Sclerosis

Exclusion criteria:

Pregnancy Breast feeding History of Diabetes, heart failure, renal failure ,hepatic failure and psychological disorder History of substance addiction Sensitivity to crocin products Clinical relapse of Multiple Sclerosis with in 30 days of screening Changes in the treatment of Multiple Sclerosis within 30 days of screening Existence of any underlying factor and disease that causes dementia and cognitive impairment

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Dentistry- Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8814187159

Approval date

2022-02-19, 1400/11/30

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.204

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Cognitive Disorder Score in MacFims Questionnaire

Timepoint

Perform MacFims test at the beginning of the study and 8 weeks after of the study

Method of measurement

MacFims Questionnaire

2

Description

Accompanying depression score

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Beck's Depression Inventory

3

Description

Accompanying anxiety score

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Beck's anxiety Inventory

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Total glutathione

Timepoint

At the beginning of the study and after 8weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Hs-CRP

Timepoint

At the beginning of the study and after 8weeks of intervention

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group: In this group of patients (n=25) will be requested to take two crocin tablets daily for 8 weeks (each tablet contain 15 mg crocin). The crocin tablets will be produced in the pharmacy faculty of Mashhad University of Medical Sciences from saffron.

Category

Treatment - Drugs

2

Description

Control group: In this group of patients (n=25) will be requested to take two placebo tablets daily for 8 weeks. The placebo tablets (Contain Avicel) will be produced in the pharmacy faculty of Mashhad University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Clinic (Shahid Beheshti hospital)

Full name of responsible person

Ebrahim Kouchaki Nasrabadi

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Bahador Rezapoor Kafteroodi
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Dr. Bahador Rezapoor Kafteroodi is committed to presenting all the achievements of the project in accordance with the framework of the National Institute for Medical Research Development in the Islamic Republic of Iran.
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available