

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of nano formulation of crocin from saffron in comparison with placebo on cognitive function, plasma level of total antioxidant capacity, malondialdehyde and glutathione reductase in plasma of patients with relapsing-remitting multiple sclerosis: A randomized triple blinded clinical trial

Protocol summary

Study aim

Investigating the effect of nano formulation of crocin from saffron on cognitive function, plasma level of total antioxidant capacity, malondialdehyde and glutathione reductase in patients with relapsing-remitting multiple sclerosis

Design

Clinical trial with placebo control group, with parallel groups, triple blinded, randomized, on 58 MS patients, randomization with blocks of size 4 using software

Settings and conduct

The place of the study: MS Research Center in Sina Hospital in Tehran; Population: relapsing remitting MS patients; type of blinding: triple blinded; blinding, randomization and preparation of supplement cans will be done by a trained person outside the study until participants, researchers and analyzer remain blind until the end of the analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the desire of the person to participate in the study; Definitive patients with RRMS based on the 2017 McDonald Diagnostic Criteria who are on file at Sina Hospital; Age 55-18, EDSS less than 5.5. Non inclusion criteria: having a neurological disease other than MS; pregnancy or breastfeeding; suffering from chronic gastrointestinal, liver, kidney, heart, respiratory and cancer; being on a diet for any reason; suffering from severe psychological disorders such as major depression; history of allergies to saffron or its compounds

Intervention groups

Intervention group: Nanocrocine supplement, 5.74 mg of crocin loaded on selenium nanoparticles in the form of two supplements with a dose of 2.87 mg daily for 12

weeks. Control group: placebo supplement, 5.74 mg of corn starch powder in the form of two supplements with a dose of 2.87 mg daily for 12 weeks.

Main outcome variables

Cognitive function, Plasma total antioxidant capacity, Malondialdehyde and Glutathione reductase activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N14**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

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

cognition performance

Timepoint

At the beginning of study and the end of 12th week

Method of measurement

BICAMS test

2**Description**

Plasma total antioxidant capacity

Timepoint

At the beginning of study and the end of 12th week

Method of measurement

Blood test

3**Description**

Plasma malondialdehyde

Timepoint

At the beginning of study and the end of 12th week

Method of measurement

Blood test

4**Description**

glutathione reductase activity

Timepoint

At the beginning of study and the end of 12th week

Method of measurement

blood test

Secondary outcomes

empty

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

Intervention group: The duration of intervention in this clinical trial will be 12 weeks. People receiving nanocrocicn supplements will receive 5.74 mg of crocin loaded on selenium nanoparticles daily in the form of two supplements at a dose of 2.87 mg.

Category

Rehabilitation

2**Description**

Control group: The duration of intervention for this group will be 12 weeks. Control group will receive placebo capsules with an equal amount of 5.74 mg of cornstarch powder in the form of two 2.87 mg daily.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina MS research center

Full name of responsible person

Soodeh Razeghi Jahromi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

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Web page address<https://nutrition.sbmu.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All data would be available to public

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

Sending email to me

Comments