Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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: Nanocrocin 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

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-01, 1400/12/10
Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
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

Public title
Effect of nano crocin on cognition among MS patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The desire of the person to participate in the study Definite dagnosis of relapsing-remitting MS based on the 2017 McDonald Diagnostic Criteria Age range 55-18 years EDSS less than 5.5 Education higher than diploma More than a month has passed since the last injection of corticosteroids (pulse therapy) More than a month has passed since the last recurrence of the disease
Exclusion criteria:
Having a neurological disease other than MS Pregnancy or breastfeeding Suffering from chronic gastrointestinal, liver, kidney, heart, respiratory and cancer diseases Being on a special diet Suffering from severe psychological disorders such as major depression History of allergies to saffron or its compounds
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study are selected by convenience sampling method. Patients are classified according to age and gender, and each person will be placed in a group receiving nanocrocin supplementation or placebo using 1:1, quadruple random blocks. Quadruple blocks are randomly designed through software such as ..... (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Assigning A or B to the supplement or placebo group will be done by someone outside the research so that the researchers remain blind. According to the list of randomly prepared quadruple blocks, a trained person outside the research team is responsible for randomly assigning patients. After each patient enters, according to the 15 quadruple blocks prepared in the first stage, each patient is randomly assigned to group A or B. Assignment process will be done consecutively until the sampling is completed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will be a three-blind clinical trial, so participants, researchers, neurologists, and data analysts will be unaware that each patient is receiving a nanocrocin supplement or placebo. In this method, one of the letters A or B will be assigned to each group, and for blindness, this will be done by the manufacturer of the supplement and placebo, and therefore we will not know the details of the groups until the end of the announcement of the results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Nutrition and Food Technology Research Institute
Street address
Hafezi Avenue, Farahzadi Blvd
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2022-02-14, 1400/11/25
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1400.096

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
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 nanocrocin 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
Street address
Imam Khomeini street
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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
Street address
Hafezi Avenue, Farahzadi Blvd
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Email
taghzieh_uni@sbmu.ac.ir
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

Full name of responsible person

Nasim Rezaeimanesh

Position

PhD candidate

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razeghi Jahromi

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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 critaria

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