

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of nano formulation of saffron crocin on depression symptoms and cognitive impairment in patients with multiple sclerosis

Protocol summary

Study aim

evaluating the effect of nano formulation of saffron crocin on depression symptoms and cognitive impairment in patients with multiple sclerosis

Design

A randomized, double-blind, placebo-controlled clinical trial with two parallel 20-member groups aiming at investigating the effect of saffron nano-crocin in improving symptoms of depression and cognitive impairment on 40 relapse remission multiple sclerosis patients

Settings and conduct

40 patients with confirmed diagnosis of RRMS by a neurologist and based on McDonalds criteria and with EDSS lower than 5.5 in addition to mild to moderate depression based on Beck Depression Inventory (BDI-II) (score 11 to 20) and other criteria of the study will be recruited in this study. These patients will be allocated to two groups (A or B) randomly using Blocked Randomization method. The intervention group will receive two nano-crocin capsules which contain 0.27 mg of nano-crocin every day for 12 weeks and placebo group will receive two capsules of placebo with the same smell and taste as nano-crocin during this period. Both patients and researchers won't be aware of the treatments patients receiving in this study. General information of the patients and their activities will be asked by researchers at the beginning of the study using general information questionnaire and the General Physical Activity Questionnaire (GPAQ). At the beginning of the study, the sixth week and the end of the study, researchers will calculate patient's depression score and cognition status using Beck Depression Inventory and MACFIMS test, respectively. At the beginning and at the end of the study, 5cc blood sample will be taken for biochemical examinations. At the sixth week of the study and at the end of the study the researchers will gather empty bottle of nano-crocin and placebo from the patients. patients will be removed from the study if they

didn't take more than 10% of the pills. We will ask all participants to keep up their routine medical treatment and normal diet without any change during the study. The efficacy of the intervention will be assessed using changes in depression severity and cognition status of RRMS patients

Participants/Inclusion and exclusion criteria

Diagnosis of relapse remission multiple sclerosis, mild to moderate depression, aged between 18 to 60 years and EDSS lower than 5.5

Intervention groups

20 relapse remission multiple sclerosis patients in nano-crocin 27 mg group 20 relapse remission multiple sclerosis patients in placebo group

Main outcome variables

Changes in Minimal Assessment of Cognitive Function in MS (MACFIMS) total score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120227009157N7**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **prospective**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Prof Mansoureh Togha

Name of organization / entity

Neurology department, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone	Target sample size: 40
+98 21 6670 2052	Randomization (investigator's opinion)
Email address	Randomized
toghae@sina.tums.ac.ir	Randomization description
Recruitment status	Due to double-blind nature of this trial, from the beginning of the study, A and B codes are available to researchers to recruit the using patients using Block Randomization (10 4-block).
Recruitment complete	Blinding (investigator's opinion)
Funding source	Double blinded
Expected recruitment start date	Blinding description
2018-04-22, 1397/02/02	Participants, main investigators and health care personnel responsible for patient care and the researchers who collect data and evaluate the outcome are being blinded to study groups, and only the producers of nanochocin are aware of the codes of the two study groups. Finally, after collecting the data, they unseal the codes for researchers, the statistical analyst, and those who prepare the manuscript.
Expected recruitment end date	Placebo
2019-04-22, 1398/02/02	Used
Actual recruitment start date	Assignment
empty	Parallel
Actual recruitment end date	Other design features
empty	40 patients with confirmed diagnosis of RRMS by a neurologist and based on McDonalds criteria and with EDSS lower than 5.5 and with mild to borderline depression based on Beck Depression Inventory (BDI-II) (score 11 to 20) and other criteria of the study will be entered to this study. These patients will be divided to two groups randomly by Blocked Randomization method. Intervention group will receive two nano-crocin capsules which contain 0.27 mg of nano-crocin every day for 12 weeks and placebo group will receive two capsules of placebo with the same smell and taste as nano-crocin during this period. Both patients and researchers won't be aware of the treatments patients receiving in this study. General information of the patients and their activities will be asked by researchers at the beginning of the study by our general information questionnaire and the General Physical Activity questionnaire (GPAQ). At the beginning of the study, the sixth week and the end of the study, researchers will calculate patient's depression score by Beck Depression Inventory. At the beginning and at the end of the study 5cc of patients blood will be taken for biochemical examinations. At the sixth week of the study and at the end of the study the researchers will gather empty bottle of nano-crocin and placelo from the patients. parients will be removed from the study if they didn't take more than 10% of the pills. We will ask from all participants to keep up their routine medical treatment and normal diet without any change during the study. The efficacy of the intervention will be assessed using Beck Depression Inventory in addition to measuring changes in depression severity of RRMS patients
Trial completion date	
empty	
Scientific title	
Effect of nano formulation of saffron crocin on depression symptoms and cognitive impairment in patients with multiple sclerosis	
Public title	
Effect of nano formulation of saffron crocin in patients with multiple sclerosis	
Purpose	
Supportive	
Inclusion/Exclusion criteria	
Inclusion criteria:	
• Willingness to participate in the study• Age range between 18 to 60 years old Diagnosis of relapse remission multiple sclerosis according to the McDonalds 2010 criteria and taking B-interferon as treatment Diagnosis of mild to moderate according to DSM V(Diagnostic and Statistical Manual of Mental Disorders, 5th edition) by a neurologist and Beck Depression Inventory (BDI-II) (score from 11 to 20) EDSS lower than 5.5	
Exclusion criteria:	
Pregnancy (or having a planned pregnancy) or Lactation Allergy or sensibility to the drugs at the beginning of their treatments History of allergy or sensibility to Saffron or its components Receiving IVIG during the last six months of treatment Increase of liver enzymes three times more than normal value Stop taking drugs for more than forth months	
Age	
From 18 years old to 60 years old	
Gender	
Both	
Phase	
0	
Groups that have been masked	
• Participant • Care provider • Investigator • Outcome assessor	
Sample size	Secondary Ids
	empty

Ethics committees

1

Ethics committee

Name of ethics committee

tehran university of medical sciences

Street address

ghods avenue, tehran university of medical sciences

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-22, 1396/11/02

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4313

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

Minimal Assessment of Cognitive Function in MS (MACFIMS) total score

Timepoint

baseline

Method of measurement

after 12-week intervention

Secondary outcomes

1

Description

total score of beck's depression inventory

Timepoint

baseline

Method of measurement

after 12-week intervention

Intervention groups

1

Description

Intervention group: intervention group will receive two nano-crocin capsules which contain 0.27 mg of nano-

crocin every day for 12 weeks

Category

Prevention

2

Description

Control group: placebo group will receive two capsules of placebo with the same smell and taste as nano-crocin during 12-week period.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

MS research center Sina hospital

Full name of responsible person

nasim rezaei manesh

Street address

Imam khomeini avenue MS research center Sina hospital tehran iran

City

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Province

Tehran

Postal code

۱۱۳۶۷۶۹۱۱

Phone

+98 21 6312 5060

Email

nassim_7189@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ms mohammdi

Street address

Imam Khomeini Hospital keshavarz boulevard

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tehran

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1419733141

Phone

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Fax**Email**

soodehrazeghi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes
Title of funding source
Tehran 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
Dr Soodeh Razeghi Jahromi
Position
Assistant professor
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Other areas of specialty/work
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Person responsible for updating data

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Prof. Mansoureh Togha
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Specialist
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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