Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-22, 1397/02/02
Expected recruitment end date
2019-04-22, 1398/02/02
Actual recruitment start date
empty
Actual recruitment end date
empty
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
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
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).
Blinding (investigator's opinion)
Double blinded
Blinding description
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.
Placebo
Used
Assignment
Parallel
Other design features
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

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 hopital
Full name of responsible person
nasim rezaei manesh
Street address
Imam khomeini avenue MS research center Sina hopital tehran iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ms mohammdi
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Imam Khomeini Hospital keshavarz boulevard
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Province
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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

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

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Position

PhD in Nutritional sciences

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Prof. Mansoureh Togha

Position

Professor of Neurology

Latest degree

Specialist

Other areas of specialty/work

Neurology

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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