# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 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**
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## Sponsors / Funding sources

### 1

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**Email**
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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**

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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)**

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