

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the saffron effect on improvement of physical and cognitive symptoms in patients with Multiple Sclerosis compared with the placebo

#### Protocol summary

##### Summary

The aim of this study is assessment of evaluating the therapeutic effects of Saffron on cognitive and physical symptoms in patients with Relapsing- Remitting Multiple Sclerosis, over a 12 months period. Relapsing-Remitting Multiple Sclerosis patients aged between 18-50 years and Expanded Disability Status Score (EDSS) between 0-5.5 will be included. This study will be undertaken in two centers in Iran (Sina Hospital and Brain and Spinal Injury Repair Research Center in Emam Khomeini Hospital) by presentation of 60 patients. These individuals are randomly divided into two groups; the intervention group receives Saffron (500 milligram three times a day, oral) and the control group receives placebo (three times a day, oral). To avoid any prejudice, both patients' groups and physicians will not be informed about the type of prescribed medication (Saffron or placebo). The patients in both groups will be evaluated and compared by the number of relapses, the change in Expanded Disability Status Score (EDSS), Multiple Sclerosis Functional Composite test (MSFC) and MRI findings. In addition, In the case of any drug allergy reaction, it will be systematically recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138802091859N1**  
Registration date: **2013-02-07, 1391/11/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-02-07, 1391/11/19

##### Registrant information

##### Name

Mohammad Ali Sahraian

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8571

##### Email address

msahrai@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice president, science and technology branch

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the saffron effect on improvement of physical and cognitive symptoms in patients with Multiple Sclerosis compared with the placebo

##### Public title

Saffron in treatment of Multiple Sclerosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients with Relapsing- Remitting Multiple Sclerosis based on McDonald's Criteria 2.age between 18-50 years old 3. Expanded Disability Status Scale (EDSS) 0- 5.5 4. Under treatment with Betaferon or Extavia 5. Signing consent form. -Exclusion criteria: 1.

Being pregnant during trial or intention to get pregnant in start of trial 2. Psychiatric disease or major depression 3. Allergy or hypersensitivity reaction to Saffron in the start of trial 4. Treatment with Intravenous immunoglobulin (IVIG) within six months prior to trial 5. Impaired Liver Function Tests (more than three times normal range) 6. Lack of medication more than four weeks.

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Randomization: Stratified Block randomization since some of the data which will be used to measure primary or secondary outcomes is gathered by physical examination, the study has been designed as a double-blind clinical trial. Knowing in which group the patient is may affect examiners' clinical judgment.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Vice Chancellor for Research ,Tehran University of Medical Sciences, Qods Street , Keshavarz Boulevard,Tehran .

**City**

Tehran

**Postal code**

-

**Approval date**

2012-01-01, 1390/10/11

**Ethics committee reference number**

90/d/130/1887

**Health conditions studied****1****Description of health condition studied**

Multiple Sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Disseminated Multiple Sclerosis

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

Relapse Rate

**Timepoint**

Before intervention and every three months after intervention

**Method of measurement**

Physical examination done by neurologist and EDSS

**Secondary outcomes****1****Description**

EDSS Expanded Disability Status Scale

**Timepoint**

Before intervention and every three months after intervention

**Method of measurement**

Physical examination done by neurologist based on revised Mc-Donald (2010)

**2****Description**

Number and size of plaques

**Timepoint**

Before intervention and every six months after intervention

**Method of measurement**

Magnetic resonance Imaging ( MRI )

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

Saffron tablet, chemical formulation the stigma of the Saffron plant, (500 milligram three times a day, oral) for 12 months, made in Drug Unit, School of Pharmacy in Tehran University of Medical Sciences in Islamic Republic Of Iran, not having generic name.

**Category**

Treatment - Drugs

2

**Description**

Placebo tablet, chemical formulation filling materials used in the preparation of pharmaceutical products (500 milligram three times a day, oral) for 12 months, made in Drug Unit, School of Pharmacy in Tehran University of Medical Sciences in Islamic Republic Of Iran.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr. Mohammad Ali Sahraian

**Street address**

Sina Hospital, before Hasan abad Square , Imam Khomeini Street

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice President, Science and Technology Branch

**Full name of responsible person**

Mr. Tawakoli

**Street address**

No.162 , south Ostad Nejatolahi street, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice President, Science and Technology Branch

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr. Amir Reza Azimi

**Position**

Neurologist

**Other areas of specialty/work**

**Street address**

Sina Hospital, before Hasan abad Square , Imam Khomeini street.

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**Web page address**

-

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr. Mohammad Ali Sahraian

**Position**

Neurologist-MS Fellowship/Associate Professor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Fatemeh Ghasemi Sakha

**Position**

researcher/master science of animal physiology

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*