Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Khomeni 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 prejudgment, 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

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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

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-

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
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Sina Hospital,before Hasan abad Square , Imam Khomeini Street
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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
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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
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

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Person responsible for updating data

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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