# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of oral herbal oil supplement (Cannabis Sativa L, Oenothera Biennis L) and advising diet with Hot nature on clinical signs and symptoms and inflammatory factors in patients with multiple sclerosis

## Protocol summary

**Summary**

The aim of this study is to investigate the effect of oral herbal oil supplement (Cannabis sativa L, Oenothera Biennis L) and advising diet with hot nature on clinical signs and symptoms and inflammatory factors in patients with multiple sclerosis (MS). In this parallel randomized controlled trial, 99 men and women with multiple sclerosis will be recruited from center of multiple sclerosis of Emam Reza Hospital of Tabriz University of Medical Sciences. The patients will be randomized to three groups to receive 18-21 g/day of supplement oil and advising diet with hot nature, 18-21 g/day of supplement oil, or 18-21g/day of "Olive Oil" as placebo. The subjects will be required to complete 3-days, 24-hour dietary record and filled in Non-quantitative Food Frequency Questionnaires for a month, two times at four-month intervals. Diets will be analyzed for Hot or Cold nature substances and other dietary items.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138804252195N1**
Registration date: **2010-12-04, 1389/09/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2010-12-04, 1389/09/13

**Registrant information**

**Name**

Mehdi Farhoudi

**Name of organization / entity**

Tabriz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Neurosciences Research Center (NSRC), Tabriz University of Medical Sciences, Yashil Daroye Sahand Company

**Expected recruitment start date**

2010-10-27, 1389/08/05

**Expected recruitment end date**

2011-01-26, 1389/11/06

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of oral herbal oil supplement (Cannabis Sativa L, Oenothera Biennis L) and advising diet with Hot nature on clinical signs and symptoms and inflammatory factors in patients with multiple sclerosis

**Public title**

Effect of oral herbal oil supplement (Cannabis Sativa L, Oenothera Biennis L) and advising diet with Hot nature on multiple sclerosis patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: All MS patients with clinical form of relapsing-remitting type, EDSS =<6 Exclusion criteria: Secondary or primary progressive MS, patients suffering

concomitantly from another chronic diseases such as active coronary heart disease, liver disease, pulmonary disease, diabetes mellitus, other neurological, inflammatory, or autoimmune diseases, Pregnancy, Corticostoid use, Acute phase of MS relapse

**Age**
From **14 years** old to **55 years** old

**Gender**
Both

**Phase**
1

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **99**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Local ethics committee, Tabriz University of Medical Sciences

**Street address**
Tabriz University of Medical Sciences, Research Vice Chancellor

**City**
Tabriz

**Postal code**

**Approval date**
2010-05-28, 1389/03/07

**Ethics committee reference number**
8920

## Health conditions studied

### 1

**Description of health condition studied**
Multiple Sclerosis

**ICD-10 code**
G35

**ICD-10 code description**
Demyelinating diseases of the central nervous system

## Primary outcomes

### 1

**Description**
serum IL-4 concentration

**Timepoint**
Before intervention -6 month after intervention

**Method of measurement**
ELISA test

### 2

**Description**
serum IFN-Y concentration

**Timepoint**
Before intervention -6 month after intervention

**Method of measurement**
ELISA test

### 3

**Description**
EDSS (Extended disability status score )

**Timepoint**
Before intervention - 3month after intervention-6 month after intervention

**Method of measurement**
Clinical examination

### 4

**Description**
urinary PLA2 concentration

**Timepoint**
Before intervention -6 month after intervention

**Method of measurement**
ELISA test

### 5

**Description**
blood cells Polyunsaturated Fatty Acid

**Timepoint**
Before intervention - 6 month after intervention

**Method of measurement**
GC test

### 6

**Description**
serum PLA2 concentration

**Timepoint**
before intervention -6month after intervention

**Method of measurement**
ELISA test

### 7

**Description**
serum IL-17 concentration

**Timepoint**
Before intervention - 6 month after intervention

**Method of measurement**
ELISA test

**8**

**Description**
blood cells delta-6-desaturase
**Timepoint**
Before intervention - 6 month after intervention
**Method of measurement**
ELISA test

## Secondary outcomes

**1**

**Description**
Changes of MRI
**Timepoint**
before intervention - 6 month after intervention
**Method of measurement**
imaging

**2**

**Description**
Drug changes of symptomatic therapy
**Timepoint**
before intervention-3month after intervention-6 month after intervention
**Method of measurement**
Interview

## Intervention groups

**1**

**Description**
Receiving 18-21g of oral supplement oil, (Cannabis Sativa L,Oenothera Biennis L), daily and advising diet with hot nature for 180 days.
**Category**
Treatment - Drugs

**2**

**Description**
Receiving 18-21g of oral supplement oil (Cannabis Sativa L,Oenothera Biennis L), daily for 180 days.
**Category**
Treatment - Drugs

**3**

**Description**
Receiving daily 18-21g of "Olive Oil" as placebo for 180 days.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Neurosciences Research Center (NSRC)
**Full name of responsible person**
Dr Mehdi Farhoudi
**Street address**
Imam Reza Medical Center-Neuro Sciences Research Center
**City**
Tabriz

**2**

**Recruitment center**
**Name of recruitment center**
Formally, Traditional Medicine Center of Yashil Daroye Sahand Company cut off its support and Neuros
**Full name of responsible person**
Soheila Rezapour Firouzi
**Street address**
17 shahrivar Aveneue, In front of Farhangian Clinic
**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Neurosciences Research Center (NSRC)
**Full name of responsible person**
Dr Mehdi Farhoudi
**Street address**
Imam Reza Medical Center- Neurosciences Research Center
**City**
Tabriz
**Grant name**
مرکز تحقیقات علوم اعصاب
**Grant code / Reference number**
89-2
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Neurosciences Research Center (NSRC)
**Proportion provided by this source**
**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*

**2**

**Sponsor**
**Name of organization / entity**
Soheila Rezapour-Firouzi
**Full name of responsible person**
Soheila Rezapour-Firouzi
**Street address**
Food and Drug Organization
**City**
Tabriz
**Grant name**
بودجه شخصی
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Soheila Rezapour-Firouzi
**Proportion provided by this source**
**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**
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Nutrition and Health Faculty
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## Person responsible for scientific inquiries

**Contact**
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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)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**

*empty*