

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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**Name of organization / entity**

Nutrition and Health Faculty

Full name of responsible person

Dr Seyed Rafi Aref Hosseini

Position

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Person responsible for scientific inquiries

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Food & Drug Organization

Full name of responsible person

Soheila Rezapour Firouzi

Position

MSC of Nutrition, student

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Person responsible for updating data

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Full name of responsible person

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Position

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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