

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Dietary Modification Based on Complementary and Alternative Iranian Medicine in Patients with Secondary-Progressive Multiple Sclerosis

Protocol summary

Study aim

Assessing The Effect of Dietary Modification Based on Complementary and Alternative Iranian Medicine in Patients with Secondary-Progressive MS.

Design

A randomized double-blind controlled clinical trial with two-arm parallel groups on 70 eligible patients (n of intervention= 35; n of control= 35)

Settings and conduct

The present study will be conducted in "577 hospital" and "Isfahan MS center". Stratified block randomization will be conducted for this trial. Blinding of participants and dieticians will not possible because of obvious differences between the intervention and control diet. The severity of clinical manifestations and the inflammation biomarkers will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: secondary-progressive MS patients (diagnosed by a neurologist according to the expanded disability status scale) who have consented to participate in the study are aged between 18-60 years old and Receive vitamin D3 50000 IU orally per week. Exclusion criteria: patients who participate in other clinical trials have particular medical conditions (type 2 diabetes, COVID-19 infection), The occurrence of MS attack, Smoking (at least two cigarettes per day), and adhering to special diets or nutritional supplements.

Intervention groups

This trial will have two parallel arms. The intervention group will receive a diet based on complementary and alternative Iranian medicine for 8 weeks (2 months). This diet contains 45-50% of energy from carbohydrates, 35% from fats, and 15-20% from proteins. The control group will continue their current diet and will receive healthy dietary recommendations and energy adjustment for 8 weeks (2 months).

Main outcome variables

Serum hs-CRP; serum ESR; quality of life; fatigue severity; pain severity; disease activity; gastrointestinal evaluation; anxiety; anthropometric indices (body weight, body mass index, percent of body fat, triceps skinfold thickness)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041641N2**
Registration date: **2022-10-08, 1401/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

Amir Reza Moravejolahkami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2022-10-23, 1401/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Dietary Modification Based on Complementary and Alternative Iranian Medicine in Patients with Secondary-Progressive Multiple Sclerosis

Public title
Complementary Medicine in Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Secondary-Progressive MS patients (diagnosed by a neurologist according to expanded disability status scale) Aged between 18-60 years old. Receiving vitamin D3 50000 IU orally per week Consent to participate in the study
Exclusion criteria:
Concurrent participation in other clinical trials COVID-19 infection Type 2 diabetes Regular intake of anti-anxiety and anti-depressant drugs The occurrence of MS attack Smoking (at least two cigarettes per day) Adherence to special diets or nutritional supplements

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified block randomization will be conducted for this trial. In the stratified block randomization method, an independent chain of random numbers (with block method) will be prepared for each stratum to assign participants of that stratum into two study groups (1. complementary/alternative diet group and 2. control group). Therefore, for each MS treatment plan determined by the neurologist (three common types of MS drugs; monoclonal antibodies, sphingosine-1-phosphate receptor modulators, and dimethyl fumarate), the random sequence will be prepared in a 1:1 ratio with letters A and B (for intervention and control groups, respectively). Random sequences will be extracted from the site (<https://www.sealedenvelope.com/>). The neurologist will determine the treatment plan of the participants, and therefore, the study group (A or B) will be determined based on the related random chain. Once

the randomization has been made, each patient is given a code with which they will be identified throughout the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this trial, blinding of participants and dieticians is not possible because of obvious differences between the intervention and control diet; however, each patient is given a code, and an employee outside of the research team will enter data into the computer in separate datasheets. Therefore, outcome assessors and data analysts will be blinded to treatment allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of AJA University of Medical Sciences

Street address
AJA university of Medical Sciences, Shahid Etemadzadeh St., West fatemi St.,

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Tehran

Province
Tehran

Postal code
1411718541

Approval date
2022-08-21, 1401/05/30

Ethics committee reference number
IR.AJAUMS.REC.1401.083

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
Serum level of high sensitivity C-Reactive Protein (hs-

CRP)

Timepoint

At baseline and 8 weeks later

Method of measurement

Chemi Luminescent ImmunoAssays (CLIAs)

2

Description

Serum Estimated Sedimentation Rate (ESR)

Timepoint

At baseline and 8 weeks later

Method of measurement

Westergren method

3

Description

Quality of life

Timepoint

At baseline and 8 weeks later

Method of measurement

Multiple Sclerosis Quality of Life (MSQOL-54) 54 items

4

Description

Disease activity

Timepoint

At baseline and 8 weeks later

Method of measurement

scoring form of Expanded Disability Status Scale (EDSS)

Secondary outcomes

1

Description

Dietary intakes of vitamins, minerals, and antioxidants

Timepoint

At baseline and 8 weeks later

Method of measurement

N4 software

2

Description

Fatigue severity

Timepoint

At baseline and 8 weeks later

Method of measurement

Modified Fatigue Impact Scale 21 items (MFIS) questionnaire

3

Description

Pain severity

Timepoint

At baseline and 8 weeks later

Method of measurement

Global Pain Scale (GPS)

4

Description

Anxiety severity

Timepoint

At baseline and 8 weeks later

Method of measurement

State-Trait Anxiety Inventory (STAI 1 and 2) 20 items

5

Description

Gastrointestinal evaluation

Timepoint

At baseline and 8 weeks later

Method of measurement

Gastrointestinal Symptom Rating Scale (GSRS) 15 items

6

Description

Body weight

Timepoint

At baseline and 8 weeks later

Method of measurement

SECA digital scale

7

Description

Body mass index

Timepoint

At baseline and 8 weeks later

Method of measurement

weight (in kilograms) divided by the square of height (in metres)

8

Description

Percent of body fat

Timepoint

At baseline and 8 weeks later

Method of measurement

Deurenberg equation

9

Description

Triceps Skinfold thickness

Timepoint

At baseline and 8 weeks later

Method of measurement

Skinfold Caliper

Intervention groups

1

Description

Intervention group. The intervention diet will be designed based on complementary and alternative Iranian medicine. The present diet will recommend the intake of

foods with moderate-nature for eight weeks (two months). Fresh vegetables and fruits, nuts, legumes, whole grains, and olive oil are the main constituents. This diet contains 45-50% of energy from carbohydrates, 35% from fats, and 15-20% from proteins. The required energy of each subject will be determined based on ideal body weight. Two education sessions will be conducted for participants, and the adherence to diet will be evaluated during two follow-up sessions.

Category

Treatment - Other

2**Description**

Control group will receive their current diet plus healthy dietary recommendations and energy adjustment for eight weeks (two months).

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

AJA Hospital

Full name of responsible person

Mahmood Rezaei

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2**Recruitment center****Name of recruitment center**

M.S Isfahan Center

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

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dr.yousefi.md@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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**

Artesh University of Medical Sciences

Full name of responsible person

Vahid Hadi

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sayid Mahdi Mirghazanfari

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The major part of the results will be available to individuals. Moreover, the datasets used and/or analyzed during the current study are available from the investigators, on reasonable request.

When the data will become available and for how long

The data will become available 8 months after the results' publication.

To whom data/document is available

The data/document is available for all individuals, on reasonable request.

Under which criteria data/document could be used

The data/document must be used for conducting similar studies and therapeutic approaches, on reasonable request from the investigators.

From where data/document is obtainable

mail to amimohs@gmail.com or
a.moravej@mail.mui.ac.ir

What processes are involved for a request to access data/document

The data will be sent as soon as possible, after receiving the request.

Comments