Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 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 intevention= 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
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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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Province

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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
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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
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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