Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of spirulina algae supplement on the quality of life, speed of nerve pulse transmission and antioxidant status of patients with progressive-recovery multiple sclerosis.

Protocol summary

Study aim

Investigating the effect of spirulina algae supplement on the quality of life, speed of nerve pulse transmission and antioxidant status of patients with progressive-recovery multiple sclerosis.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The present study will be a double-blind clinical trial in Isfahan city on patients with progressive-recovery MS in two intervention and control groups with random blinding method. Personal, demographic, anthropometric, economic-social information, quality of life and work and food intake will be evaluated by questionnaire. In order to measure the speed of nerve message transmission, visual induction potential test will be used. Changes in the antioxidant level of the body will be checked by biochemical kits. The amount of spirulina supplement (intervention) and placebo (control) will be 1000 mg for 12 weeks.

Participants/Inclusion and exclusion criteria

Criteria for entering the study Patients with MS of RRMS type Age of patients 18-50 years Having an Extended Disability Status Scale (EDSS) between 0 and 6 Criteria for not entering the study: Pregnant, lactating and hospitalized participants History of viral diseases, asthma, and other autoimmune diseases that affect the Th1/Th2 balance obese patients (body mass index (BMI) ≥ 30 kg/m2), malnourished patients (BMI < 18.5 kg/m2) Not taking anticoagulants

Intervention groups

The intervention group includes patients with progressive-relapsing MS with an EDSS score of 0-6 who receive spirulina supplements. The control group includes patients with progressive-remitting MS with an EDSS score of 0-6 who receive a placebo.

Main outcome variables

Improving patients' quality of life, antioxidant status and speed of nerve message transmission

General information

Reason for update

Evaluation of interleukins IL-1 and IL-6 in the patients' serum has been added, which does not affect the intervention process and is only considered an additional evaluation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240124060794N1**
Registration date: **2024-02-04, 1402/11/15**
Registration timing: **prospective**

Last update: **2024-12-08, 1403/09/18**
Update count: **1**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name
Sheno Karimi
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
2024-04-18, 1403/01/30
Expected recruitment end date
2024-06-19, 1403/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of spirulina algae supplement on the quality of life, speed of nerve pulse transmission and antioxidant status of patients with progressive-recovery multiple sclerosis.

Public title
The effect of spirulina supplementation on MS
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with MS of RRMS type Age of patients 18-50 years Receiving immunosuppressive drugs for at least three months Not taking multivitamin supplements (except vitamin D) at least 3 months before participating in the study Having an Extended Disability Status Scale (EDSS) between 0 and 6
Exclusion criteria:
Pregnancy Presentation of acute forms of liver and biliary system disease and pancreatic disease History of viral diseases Chronic renal or cardiovascular disease and diseases where oxidative stress is considered as their etiology Obese patients (body mass index (BMI) ≥ 30 kg/m2), malnourished patients (BMI < 18.5 kg/m2) Dependence on drugs, smoking or alcohol Not taking anticoagulants Breastfeeding Hospitalized Autoimmune diseases that affect the Th1/Th2 balance Asthma Diseases in which oxidative stress is proposed as their etiology
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the random sequence will be determined using the simple randomization method using www.sealedenvelope.com. Based on the sample size, people will be placed in two intervention and control groups with a specific code and following the concealment process. Each patient will be assigned a unique code. The specific code will be determined by a third person, and the researcher and the participant do not know to which person each code will be assigned and in which group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug and placebo are provided to both groups in completely similar containers without name labels, which are prepared in the same color and smell and coded based on random allocation by the project partner, so none of the patients and the researcher were aware of the assigned treatment and until the end The study will not be informed The random allocation list of patients will be in the sole possession of an individual outside the plan. In order to hide the random allocation process, random codes are written on the paper label without a specific order and framework, which is the identification number of the relevant treatment and only a person outside the plan will be aware of the relevant code. The labels will be stuck on the medicine packages in the order of the randomization list. Medicine packages will be arranged in the order of the randomization list inside the box. When a patient's eligibility is determined, the researcher will provide the patient with a treatment plan.
Placebo
Used
Assignment
Parallel
Other design features
Evaluation of the improvement of the transmission of nerve messages by measuring the visual evoked potential, following supplementation with spirulina

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hezar Jerib Avenue, Isfahan
City
Esfahan
Province
Isfehan
Postal code
73461-81746
Approval date
2024-01-20, 1402/10/30
Ethics committee reference number
IR.MUI.PHANUT.REC.1402.070

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
Investigating antioxidant status
Timepoint
Before and after supplementation
Method of measurement
Biochemical kit for measurement of antioxidant level

2

Description
Investigating the quality of life and work
Timepoint
Before and after supplementation
Method of measurement
Quality of life questionnaire

3

Description
Investigating the speed of nerve transmission
Timepoint
Before and after supplementation
Method of measurement
Skin electrode

4

Description
Investigating the inflammation status
Timepoint
Before and after supplementation
Method of measurement
IL-1 and IL-6 measurement by ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: spirulina algae supplement, 500 mg capsules, twice a day for three months, consumption after the main meal, Spiro Company (Bushehr-Iran).
Category
Rehabilitation

2

Description
Control group: Placebo capsules containing corn starch, twice a day for three months, consumed after the main meal, Spiro Company (Bushehr-Iran).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Vahid Shaigan Nezhad
Street address
Kashani St., Kashani Hospital, Isfahan
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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
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector

Public

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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Hasan Entezari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the commitment to the confidentiality of the personal information of the people in the consent form, there is no plan to publish it.

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable