Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of allicin supplementation on inflammation, oxidative stress and clinical symptoms in patients with multiple sclerosis

Protocol summary

Study aim

To determine the effects of allicin supplementation on inflammatory and oxidative stress biomarkers, and neurological, metabolic, and psychological clinical parameters in patients with relapsing-remitting multiple sclerosis (RRMS).

Design

Phase III randomized, double-blind, placebo-controlled, parallel-group trial with 76 participants (38 per group). Randomization was done using permuted blocks of 4 and 6 via Sealed Envelope.

Settings and conduct

Patients recruited from the Multiple Sclerosis Society of Ahvaz. Baseline and week-10 clinical, neurological, biochemical, and questionnaire assessments conducted. Randomization and blinding applied for participants and researchers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18–55 years, confirmed diagnosis of RRMS by a neurologist based on the 2017 McDonald criteria, EDSS score ≤ 5.5, ability and willingness to provide informed consent, and adherence to daily supplementation. Exclusion criteria: known allergy to garlic, history of severe gastrointestinal disorders, uncontrolled psychiatric disorders, presence of other autoimmune diseases, active malignancy, use of medications affecting inflammation, oxidative stress, or coagulation, recent change in MS medications or corticosteroid use within the past 3 months, active infection or systemic illness at baseline, pregnancy or breastfeeding, and inability or unwillingness to cooperate with study procedures.

Intervention groups

Intervention group: 2 Dineh garlic tablets/day for 10 weeks (400 mg dried garlic powder, 1.1 mg allicin per tablet; Dinehiran Co., Qazvin, Iran). Placebo group: identical corn-starch tablets produced by the same company, administered on the same schedule.

Main outcome variables

Inflammation, Oxidative stress, Clinical outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251126068121N1**
Registration date: **2025-12-08, 1404/09/17**
Registration timing: **prospective**

Last update: **2025-12-08, 1404/09/17**
Update count: **0**

Registration date

2025-12-08, 1404/09/17

Registrant information

Name

Ali Keshavarz

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-25, 1404/10/04

Expected recruitment end date

2026-07-27, 1405/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of allicin supplementation on inflammation, oxidative stress and clinical symptoms in patients with multiple sclerosis

Public title
The effect of Allicin Supplementation on MS

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Adults aged 18–55 years Confirmed diagnosis of RRMS (2017 McDonald criteria) EDSS score ≤ 5.5 Ability and willingness to provide informed consent Ability to adhere to daily supplementation

Exclusion criteria:
Known allergy to garlic History of severe gastrointestinal disorders Uncontrolled psychiatric disorders Active malignancy Presence of other autoimmune diseases Use of medications affecting coagulation or platelet function change in MS medications or corticosteroid use within the past 3 months Active infection or systemic illness at the time of enrollment Pregnancy or breastfeeding Inability or unwillingness to cooperate with study procedures

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with variable block sizes of 4 and 6 in a 1:1 allocation ratio will be used for randomization. An independent researcher will generate the random sequence by the Sealed Envelope online system (https://www.sealedenvelope.com/simple-randomiser/v1/lists), and allocation will be hidden by using the consecutively numbered, non-transparent, sealed envelopes each of which will have a unique alphanumeric code corresponding to the intervention container labeled. A team member, who is not involved in recruitment or assessment, will assign participants to the allicin or placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind. Participants and outcome assessment (including neurologist performing EDSS and T25FW evaluations) will remain blinded to group allocation. Care providers and laboratory personnel will also not be informed of treatment assignments to maintain blinding integrity.

Placebo
Used

Assignment
Parallel

Other design features
This trial is the first to assess the effects of allicin supplementation on oxidative stress, inflammation, and clinical outcomes in patients with multiple sclerosis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ethics Committee, Ahvaz Jundishapur University of Medical Sciences, Golestan Avenue, Ahvaz, Iran

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Ahvaz

Province
Khouzestan

Postal code
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Approval date
2025-11-08, 1404/08/17

Ethics committee reference number
IR.AJUMS.REC.1404.438

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
Total Antioxidant Capacity (TAC)

Timepoint
At the beginning of the study and 10 weeks after the intervention.

Method of measurement
Laboratory kit

Secondary outcomes

1

Description
Interleukin 6 (IL-6)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Laboratory kit

2

Description
C-reactive protein (CRP)
Timepoint
At the beginning of the study and 10 weeks after the intervention
Method of measurement
immunoturbidimetric assay using an automated analyzer.

3

Description
Erythrocyte Sedimentation Rate (ESR)
Timepoint
At the beginning of the study and 10 weeks after the intervention
Method of measurement
Westergren method

4

Description
Malondialdehyde (MDA)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Laboratory kit

5

Description
Glutathione Peroxidase (GPx)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Laboratory kit

6

Description
Superoxide Dismutase (SOD)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Laboratory kit

7

Description
Timed 25-Foot Walk (T25-FW)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Assessed by a neurologist.

8

Description
Expanded Disability Status Scale (EDSS)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Assessed by a neurologist (McDonald criteria)

9

Description
Fasting Blood Sugar
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Enzymatic

10

Description
Lipids profile (Total-C, TG, HDL-C, LDL-C)
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Enzymatic colorimetric methods for TC, TG, and HDL-C. LDL-C will be calculated using the Friedewald's formula: LDL-C = TC − HDL-C − (TG/5).

11

Description
Blood pressure
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
BEURER-BM44 digital blood pressure monitor

12

Description
Pain intensity
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Visual Analog Scale (VAS)

13

Description
Fatigue severity
Timepoint
At the beginning of the study and 10 weeks after the intervention
Method of measurement
Questionnaire of Fatigue Severity Scale (FSS)

14

Description
Sleep quality
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
PSQI questionnaire

15

Description
General mental health
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
General health questionnaire - 28 (GHQ-28)

16

Description
Quality of life score
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
SF-36 questionnaire

17

Description
Weight
Timepoint
At the beginning of the study and 10 weeks after the intervention
Method of measurement
Using scales

18

Description
Body mass index
Timepoint
At the beginning of the study and 10 weeks after the intervention.
Method of measurement
Weight in kilograms divided by height in meters squared.kg/m2

19

Description
Dietary intake
Timepoint
At the beginning of the study, at week 5, and 10 weeks after the intervention.
Method of measurement
using Nutritionist IV software

Intervention groups

1

Description
Intervention group: Participants will receive two 2 Dineh garlic tablets daily for 10 weeks (one after lunch and one after dinner). Each tablet contains 400 mg dried garlic powder standardized to 1.1 mg allicin, providing a total daily dose of 2.2 mg allicin. The supplement is manufactured by Dinehiran Company (Qazvin, Iran).
Category
Treatment - Drugs

2

Description
Control group: Participants will receive corn-starch–based placebo tablets identical in shape, size, color, taste, and packaging to the active supplement, manufactured by Dinehiran Company (Qazvin, Iran), taken on the same schedule.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khouzestan Multiple Sclerosis Society
Full name of responsible person
Dr. Nastaran Majdinasab
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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
Ahvaz 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
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Full name of responsible person
Ali Keshavarz
Position
M.Sc student of Nutrition Science
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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

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