

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of ginger consumption on serum levels of neurofilament light polypeptide, matrix metalloproteinase-9, interleukin-17, nitric oxide metabolites, and differential leukocyte count and score of disability status, quality of life, and gastrointestinal symptoms in patients with multiple sclerosis: a double-blind randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of ginger consumption on serum levels of neurofilament light polypeptide, matrix metalloproteinase-9, interleukin-17, nitric oxide metabolites, and differential leukocyte count and score of disability status, quality of life, and gastrointestinal symptoms in patients with multiple sclerosis

Design

This study will be a parallel double-blind randomized controlled clinical trial with a sample size of 50 people. The randomization will be done using a web-based randomization service.

Settings and conduct

Fifty patients with multiple sclerosis will be recruited from Imam Reza Clinic, Shiraz, Iran. The intervention and control groups will receive ginger and placebo supplements for 12 weeks, respectively. Ginger and placebo supplements will be the same in terms of packaging, shape, color, smell, and size. Participants, care providers, investigators, and outcome assessors will be blinded. The main outcomes will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Having relapsing-remitting multiple sclerosis according to the 2017 revisions of the McDonald diagnostic criteria 2) Age between 18-50 years 3) Disability status score of less than or equal to 4.5 based on Expanded Disability Status Scale. Exclusion criteria: 1) Having other serious diseases such as other autoimmune disorders or cancers 2) Pregnancy 3) Consumption of less than 90% of ginger or placebo supplements

Intervention groups

1) Intervention group: 500 mg ginger supplements three

times a day for 12 weeks. 2) Control group: 500 mg corn supplements (placebo) three times a day for 12 weeks

Main outcome variables

Neurofilament light polypeptide, matrix metalloproteinase-9, interleukin-17, nitric oxide metabolites, differential leukocyte count, disability status, quality of life, gastrointestinal symptoms, hematological indices, and body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N3**

Registration date: **2021-10-06, 1400/07/14**

Registration timing: **prospective**

Last update: **2021-10-06, 1400/07/14**

Update count: **0**

Registration date

2021-10-06, 1400/07/14

Registrant information

Name

Reza Amnai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1378

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r_amani@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ginger consumption on serum levels of neurofilament light polypeptide, matrix metalloproteinase-9, interleukin-17, nitric oxide metabolites, and differential leukocyte count and score of disability status, quality of life, and gastrointestinal symptoms in patients with multiple sclerosis: a double-blind randomized controlled clinical trial

Public title

The effect of ginger consumption in patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having relapsing-remitting multiple sclerosis according to the 2017 revisions of the McDonald diagnostic criteria
Age between 18-50 years
Non-menopausal women
Disability status score of less than or equal to 4.5 based on Expanded Disability Status Scale
No multiple sclerosis attack or corticosteroid therapy for at least 30 days
No change in multiple sclerosis medications for at least 6 months
Ability and willingness to participate in the study

Exclusion criteria:

Having other serious diseases such as other autoimmune disorders or cancers
Pregnancy
Multiple sclerosis attack or corticosteroid therapy during the intervention
Change in multiple sclerosis medications during the intervention
Allergic reactions to ginger or placebo supplements
Consumption of less than 90% of ginger or placebo supplements

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to intervention and control groups using stratified permuted block randomization (block size = 4, allocation ratio = 1:1). Stratification will be done according to gender. The following website will be used for generation of random allocation sequence: <https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

Ginger and placebo supplements will be the same in terms of packaging, shape, color, smell, and size.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.248

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

Score of disability status

Timepoint

Before and after the intervention

Method of measurement

Expanded Disability Status Scale

2**Description**

Serum levels of interleukin-17

Timepoint

Before and after the intervention

Method of measurement

Assay kit

3**Description**

Serum levels of nitric oxide metabolites

Timepoint

Before and after the intervention

Method of measurement

Assay kit

Secondary outcomes**1****Description**

Serum levels of neurofilament light polypeptide

Timepoint

Before and after the intervention

Method of measurement

Assay kit

2**Description**

Serum levels of matrix metalloproteinase-9

Timepoint

Before and after the intervention

Method of measurement

Assay kit

3**Description**

Differential leukocyte count

Timepoint

Before and after the intervention

Method of measurement

Cell counter machine

4**Description**

Score of quality of life

Timepoint

Before and after the intervention

Method of measurement

Multiple Sclerosis Impact Scale

5**Description**

Score of gastrointestinal symptoms

Timepoint

Before and after the intervention

Method of measurement

Visual Analogue Scale

6**Description**

Hematological indices

Timepoint

Before and after the intervention

Method of measurement

Cell counter machine

7**Description**

Body mass index

Timepoint

Before and after the intervention

Method of measurement

Weighing scale and measuring tape

Intervention groups**1****Description**

Intervention group: 500 mg ginger supplements three times a day for 12 weeks

Category

Treatment - Other

2**Description**

Control group: 500 mg corn supplements (placebo) three times a day for 12 weeks

Category

Placebo

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

Imam Reza Clinic

Full name of responsible person

Dr. Maryam Poursadeghfard

Street address

Namazi Sq.

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Shiraz

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Fars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooy Javanmard

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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

Reza Amani

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be available upon reasonable request from Prof. Reza Amani.

When the data will become available and for how long
12 months after publication of results
To whom data/document is available
Academic users
Under which criteria data/document could be used
Academic purposes
From where data/document is obtainable
r_amani@nutr.mui.ac.ir
What processes are involved for a request to access data/document
Upon receipt of the request, the data will be sent as soon as possible.
Comments