Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Oct 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/lists
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
Isfehan
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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Province
Fars
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71348-14734
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Email
poursadra@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjooy Javanmard
Street address
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Province
Isfehan
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81746-73461
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+98 31 3668 8138
Email
sh_haghjoo@med.mui.ac.ir
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