Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on disease severity, mental health, insulin resistance, inflammatory factors and biomarkers of oxidative stress in patients with multiple sclerosis

Protocol summary

Study aim

The aim of this study is to determine the effects of probiotic supplementation on disease severity, mental health, insulin resistance, inflammatory factors and biomarkers of oxidative stress in patients with multiple sclerosis.

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. 48 patients with multiple sclerosis of eligible in the study will be selected. Patients will be assigned to receive either probiotic supplements and placebo. Fasting blood samples will be taken at baseline and after 16-wk intervention.

Settings and conduct

Patients with multiple sclerosis of eligible and referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

The inclusion criteria were patients with ages between 20 and 60, course of disease relapsing–remitting MS (RRMS), identified according to McDonald criteria and an expanded disability status scale (EDSS) score ≤4.5 referred to the Neurology Clinic of Shahid Beheshti Hospital in Kashan city, Iran. The exclusion criteria were primary progressive MS (PPMS), secondary progressive MS (SPMS), clinical relapse and glucocorticoid therapy during the past one month, pregnancy, women who were lactating within the prior six month, patients with bearing nephrolithiasis within the prior five years and consumers of probiotic or synbiotic during the past three month.

Intervention groups

Patients will be assigned to receive either probiotic supplements (intervention group: n=24) and placebo (control group: n=24).

Main outcome variables

Disease severity, mental health, insulin resistance, inflammatory factors and biomarkers of oxidative stress will be measured at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082234497N2**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-14, 1398/06/23**
Update count: **1**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name
Omid Reza Tamtaji
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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tamtaji-or@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2017-08-17, 1396/05/26
Expected recruitment end date
2017-09-17, 1396/06/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic supplementation compared with the placebo on disease severity, mental health, insulin resistance, inflammatory factors and biomarkers of oxidative stress in patients with multiple sclerosis

Public title
Effect of supplementation in treatment of patients with multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with multiple sclerosis identified according to McDonald criteria Course of disease relapsing–remitting MS (RRMS) EDSS ≤4.5
Exclusion criteria:
Primary progressive MS (PPMS) Secondary progressive MS (SPMS) Relapse and glucocorticoid therapy during the past one month Pregnancy Women who were lactating within the prior six month Nephrolithiasis Consumption of of probiotic or synbiotic during the past three month
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either probiotic supplements (n = 24) or placebo (n = 24). Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shahid Beheshti Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.
Placebo
Used
Assignment
Parallel
Other design features
Random assignment will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2017-08-16, 1396/05/25
Ethics committee reference number
IR.Kaums.MEDNT.REC.1396.28

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
EDSS
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
Physical Examination by Neurologist

2

Description

high sensitivity C-reactive protein

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA

2

Description

Fasting blood sugar

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Nitric oxide

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Interleukin 6

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA kit

5

Description

Interleukin 10

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA kit

6

Description

Tumor necrosis factor alpha

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA kit

7

Description

8-hydroxydeoxyguanosine

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA kit

8

Description

Superoxide dismutase

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

ELISA kit

9

Description

Glutathione

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Spectrophotometry

11

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement

Spectrophotometry

12

Description

Depression

Timepoint

At the beginning of the study and after 16 weeks of intervention

Method of measurement
Beck Depression Inventory

13

Description
General Health
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
General Health Questionnaire (28 item)

14

Description
Depression
Timepoint
At the beginning of the study and after 16 weeks of intervention
Method of measurement
depression, anxiety and stress scale

Intervention groups

1

Description
Intervention group: Probiotic capsule containing four strains of Bifidobacterium infantis (2×109 CFU/g), Lactobacillus reuteri (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g), lactobacillus plantarum (2×109 CFU/g), lactobacillus fermentum (2×109 CFU/g), and bifidobacterium lactis (2×109 CFU/g), daily, for 16 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, daily, for 16 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Shahid Beheshti Hospital
Full name of responsible person
Ebrahim Kouchaki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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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
Vice chancellor for research, Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
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Person responsible for updating data

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MSc student of medical physiology

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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