Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on levels of gene expression related with glycemic control, lipid and inflammatory factors in patients with multiple sclerosis

Protocol summary

Study aim
The aim of this study is to determine the effects of probiotic supplementation on levels of gene expression related with glycemic control, lipid and inflammatory factors in in patients with multiple sclerosis.

Design
Parallel double-blind (both patients and researchers) randomized controlled clinical trial

Settings and conduct
40 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
Patients with multiple sclerosis and aged 18 to 55 years will be included in this study. The participants will be excluded from the study under following conditions: women who were pregnant or lactating during the past six months, taking probiotic or synbiotic products, menopaused women with irregular menstruation and unwillingness to utilize appropriate contraceptive tools.

Intervention groups
Patients will be assigned to receive either probiotic (n=20) or placebo (n=20).

Main outcome variables
Levels of gene expression related with glycemic control, lipid and inflammatory factors

General information

Reason for update
The updating process was done after publishing the paper to correct the registration information.

Acronym

IRCT registration information
IRCT registration number: **IRCT201609185623N88**
Registration date: **2016-09-27, 1395/07/06**
Registration timing: **retrospective**

Last update: **2023-04-03, 1402/01/14**
Update count: **2**

Registration date
2016-09-27, 1395/07/06

Registrant information

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Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2016-07-24, 1395/05/03

Expected recruitment end date
2016-07-31, 1395/05/10

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 levels of gene expression related with glycemic control, lipid and inflammatory

factors 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 Aged 18 to 55 years Course of disease relapsing–remitting MS (RRMS) EDSS ≤4.5
Exclusion criteria:
Pregnancy Women who were lactating within the prior six month Consumption of of probiotic or synbiotic Menopaused women with irregular menstruation Unwillingness to utilize appropriate contraceptive tools
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
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 = 20) or placebo (n = 20). 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

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
2016-07-23, 1395/05/02
Ethics committee reference number
IR.Kaums.REC.1395.42

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
Tumor necrosis factor alpha
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Interleukin 1
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

3

Description
Interleukin-8
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Secondary outcomes

1

Description
Peroxisome proliferator–activated receptor γ (PPARγ)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Low Density Lipoprotein Receptor (LDLR)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: Probiotic capsule containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g), Bifidobacterium bifidum (2×109 CFU/g) and Lactobacillus fermentum (2×109 CFU/g) (Tak Gen Zist, Tehran, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Zatollah Asemi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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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
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
Position
Nutritionist
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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