Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on metabolic profiles in patients with multiple sclerosis

Protocol summary

Study aim
he aim of this study is to determine the effects of probiotic supplementation on disease severity and metabolic profiles 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.

Settings and conduct
60 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
Peoples will be entered in the study if they will be at ages between 18 and 55 with clinically definite RRMS will be diagnosed according to McDonald criteria and an expanded disability status scale (EDSS) score ≤4.5. The participants will be excluded from the study under following conditions: women who were pregnant or lactating during the past six months, patients bearing nephrolithiasis for the past 5 years, menopaused women with irregular menstruation and unwillingness to utilize appropriate contraceptive tools.

Intervention groups
Patients will be assigned to receive either probiotic supplements (intervention group: n=30) and placebo (control group: n=30).

Main outcome variables
Fasting blood samples will be taken at baseline and after 12-wk intervention. Disease severity and metabolic profiles will be meseaured at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201511015623N59**
Registration date: **2015-12-02, 1394/09/11**
Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**
Update count: **1**

Registration date
2015-12-02, 1394/09/11

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2015-11-01, 1394/08/10

Expected recruitment end date
2015-12-01, 1394/09/10

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 metabolic profiles in patients with multiple sclerosis

Public title
Effect of supplementation in treatment of patients with multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ages between 18 and 55 The course of RRMS diagnosed according to McDonald criteria EDSS score ≤4.5
Exclusion criteria:
Women who were pregnant Lactating during the past six months Nephrolithiasis for the past 5 years 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: **60**
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 = 30) or placebo (n = 30). 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 Clinic of Shahid Beheshti Hospital , 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
81151-87159
Approval date
2015-10-28, 1394/08/06
Ethics committee reference number
IR.Kaums.REC.1394.81

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 12 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 12 weeks of intervention
Method of measurement
ELISA kit

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

Elisa kit

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

10

Description
General health
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Standard questionnaire GHQ-28

11

Description
Depression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
depression, anxiety and stress scale

12

Description
Depression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Beck Depression Inventory

Intervention groups

1

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), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, 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
Ebrahim Kouchaki
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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Ghotbe Ravandi Boulevard, Kashan
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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
Latest degree
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Person responsible for updating data

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Full name of responsible person
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Position
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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