

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

The 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  $\leq 4.5$ . 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, menopausal 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 measured 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)

##### Phone

+98 36 1534 3570

##### Email address

asemi\_z@kaums.ac.ir

#### 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  $\leq 4.5$

#### Exclusion criteria:

Women who were pregnant Lactating during the past six months Nephrolithiasis for the past 5 years Menopausal 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

Isfahan

##### 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 (2×10<sup>9</sup> CFU/g), Lactobacillus casei (2×10<sup>9</sup> CFU/g), Bifidobacterium bifidum (2×10<sup>9</sup> CFU/g) and Lactobacillus fermentum (2×10<sup>9</sup> 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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**Phone**

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beheshtihospital@kaums.ac.ir

**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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research@kaums.ac.ir

**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**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

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## Web page address

## 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