

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 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, menopausal women with irregular menstruation and unwillingness to utilize appropriate contraceptive tools.

Intervening 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

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

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
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: **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

Isfahan

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 (PPAR γ)

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 $\times$ 10⁹ CFU/g), *Lactobacillus casei* (2 $\times$ 10⁹ CFU/g), *Bifidobacterium bifidum* (2 $\times$ 10⁹ CFU/g) and *Lactobacillus fermentum* (2 $\times$ 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

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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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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 scientific inquiries

Contact

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Zatollah Asemi
Position
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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