Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of probiotic supplementation on gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive probiotic supplement (n=25) or placebo (n=25).

Settings and conduct

Among patients with Parkinson's disease referred to Neurology Clinic, 50 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Parkinson' disease; aged 50 to 80 years. Exclusion criteria: Taking probiotics and/or synbiotics supplements, taking antioxidants supplements and anti-inflammatory agents, had depression and had severe psychosis, hypothyroidism, hyperthyroidism, and smokers.

Intervention groups

Intervention group: Probiotic oral capsule containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus reuteri (2×109 CFU/g), Bifidobacterium bifidum (2×109 CFU/g) and Lactobacillus fermentum (2×109 CFU/g), daily, for 12 weeks. Control group: Placebo oral capsule (Barij Essence, Kashan, Iran) , daily, for 12 weeks.

Main outcome variables

Outcomes: Gene expression related to inflammation (primary outcomes) and inflammatory factors, markers of oxidative stress and gene expression related to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N34**
Registration date: **2018-06-14, 1397/03/24**
Registration timing: **retrospective**

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

Registration date

2018-06-14, 1397/03/24

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-16, 1396/07/24

Expected recruitment end date

2017-10-31, 1396/08/09

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 gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease

Public title
Effect of probiotic supplementation in treatment of patients with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients with Parkinson' disease. Individuals aged 50 to 80 years.
Exclusion criteria:
Taking probiotics and/or synbiotics supplements Taking antioxidants supplements and anti-inflammatory agents Had depression Had severe psychosis Hypothyroidism Hyperthyroidism Smokers
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
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 receive supplement or placebo. Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University
Street address
Islamic Azad University, Science and Research Branch, Daneshgah SQ, Tehran
City
Tehran
Province
Tehran
Postal code
1771844351
Approval date
2017-10-15, 1396/07/23
Ethics committee reference number
IR.IAU.SRB.REC.1396.72

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Expressed levels of TNF-a gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Expressed levels of IL-1 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

3

Description
Expressed levels of IL-8 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

PCR

Secondary outcomes

1

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

2

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

3

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

4

Description
Expressed levels of LDLR gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of VEGF gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of TGF-β gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: Probiotic oral capsule containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus reuteri (2×109 CFU/g), Bifidobacterium bifidum (2×109 CFU/g) and Lactobacillus fermentum (2×109 CFU/g), daily, for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo oral capsule (Barij Essence, Kashan, Iran) , daily, for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Reza Daneshvar
Street address
Ghotbe Ravandi Boulevard, Kashan
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Isfehan
Postal code
81151-87159
Phone
+98 31 5554 0026
Email
reza.daneshvar22@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Fatemeh Azizabadi Farahani
Street address
Islamic Azad University, Science and Research Branch, Daneshgah SQ, Tehran
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f_farahany@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

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