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 Parkinson's

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 Parkinson's.

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

Settings and conduct

60 eligible patients with Parkinson's and referred to Shahid Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected for the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Parkinson's and aged 50 to 90 years will be included in this study. Exclusion criteria were were taking antioxidants supplements and anti-inflammatory medications, depression and severe psychosis, hypo- and hyperthyroidism, smoking and unwillingness to cooperate.

Intervention groups

Intervention group: Probiotic 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) (Zisttakhmir Company, Tehran, Iran) daily, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) daily for 12 weeks orally

Main outcome variables

Unified Parkinson's disease rating scale (UPDRS) and high sensitivity C-reactive protein (primary outcomes), fasting plasma glucose, insulin, insulin resistance, lipid profiles and oxidative stress (secondary outcomes)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082434497N4**
Registration date: **2017-09-06, 1396/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-11, 1398/06/20**
Update count: **1**

Registration date

2017-09-06, 1396/06/15

Registrant information

Name
Omid Reza Tamtaji
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-08-17, 1396/05/26

Expected recruitment end date

2017-09-17, 1396/06/26

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 Parkinson's

Public title
Effect of supplementation in treatment of patients with Parkinson's

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Parkinson's Aged 50 to 90 years

Exclusion criteria:
Taking antioxidants supplements Taking anti-inflammatory supplements Depression Severe psychosis hypo- and hyperthyroidism Smoking

Age
From **50 years** old to **90 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
Participants in each block will be randomly allocated into two treatment groups to take either probiotic supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. https://stattrek.com/statistics/random-number-generator.aspx

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. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

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
2017-08-16, 1396/05/25

Ethics committee reference number
IR.Kaums.MEDNT.REC.1396.29

Health conditions studied

1

Description of health condition studied
Parkinson disease

ICD-10 code
G20

ICD-10 code description
Parkinson disease

Primary outcomes

1

Description
high sensitivity C-reactive protein (hs-CRP)

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa kit

2

Description
Unified Parkinson's disease rating scale

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Physical Examination by Neurologist

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

3

Description
Total cholesterol
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

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) (Zisttakhmir Company, Tehran, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Neurology Clinic
Full name of responsible person
Reza Daneshvar
Street address
Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, 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
Vice chancellor for research, 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
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Zatollah Asemi
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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