Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the effect of synbiotic supplementation on antioxidant and inflammatory markers, serum zonulin level and quality of life in patients with Parkinson's disease

Protocol summary

Study aim

Evaluation of the effect of synbiotic supplementation on antioxidant and inflammatory markers, serum zonulin level and quality of life in patients with Parkinson's disease

Design

this is a randomized, double blind, parallel, placebo-controlled clinical trial, in which 80 Parkinson's disease will be divided into two groups: receiving synibiotics and Parkinson's appropriate diet or placebo and Parkinson's appropriate diet

Settings and conduct

Participants will be selected among Parkinson's disease referred to Imam Musa Sadr Clinic in Isfahan and will be randomly divided into two groups intervention and placebo and will be studied for 12 weeks. Supplements and placebo will be packed in similar boxes. To double-blind this study, treatment and placebo packets will be coded as A and B By someone other than the researcher prior to study initiation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: agree to participate in the study, diagnosis of Parkinson's disease according to the criteria of the Parkinson's Disease Association, age 50 to 80 years pataints will not be include if: intake of products enriched with probiotics, prebiotics or their supplements, antibiotics or laxatives, antioxidant supplements, history of Gastrointestinal surgery or disease, hypothyroidism or hyperthyroidism, neurological diseases, smoking, type 1 and 2 diabetes, use of anti-inflammatory or immunosuppressants drug, Hoehn and Yahr score of 5 out of 5

Intervention groups

The intervention group will receive 5 g/d synbiotic supplement and Parkinson's appropriate diet and control group will receive 5 g/d maltodextrin , and Parkinson's appropriate diet

Main outcome variables

symptoms of disease by MDS-UPDRS, Hoehn and Yahr score, inflammatory markers, total antioxidant and oxidant capacity, Malondiadehyde, glutathione, quality of life, zonulin,lipopolysaccharide(endotoxin), depression, anxiety,fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N2**
Registration date: **2021-03-16, 1399/12/26**
Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**
Update count: **0**

Registration date

2021-03-16, 1399/12/26

Registrant information

Name

Reza Amnai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1378

Email address

r_amani@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-12, 1400/01/23

Expected recruitment end date

2021-07-14, 1400/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of synbiotic supplementation on antioxidant and inflammatory markers, serum zonulin level and quality of life in patients with Parkinson's disease

Public title

The effect of synbiotic supplementation on Parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who agree to participate in the study Diagnosis of Parkinson's by a neurologist based on the diagnostic criteria of the Parkinson's Disease Association (UK Parkinson's disease society Brain Bank criteria) Age 50 to 80 years

Exclusion criteria:

Regular consumption of products fortified with probiotics and prebiotics, probiotic and prebiotics supplements at least 2 months before start of the study Take antibiotics or laxatives at least 2 months before the start of the study Take antioxidant supplements or supplements that affect the disease Having a history of gastrointestinal surgery History of chronic gastrointestinal disease, hypothyroidism or hyperthyroidism, severe psychosis, or other concomitant neurological diseases, cognitive impairment, smoking or nicotine or alcohol use Having a history of type 1 and 2 diabetes Taking anti-inflammatory and immunosuppressive drugs Sensitivity to the compounds in the supplement Having hoehn and yahr score of 5 out of 5

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by stratified Permuted Block Randomization, via the website, https://www.sealedenvelope.com/simple-randomiser/v1/lists. Each block has capacity for two subjects. Subjects will be stratified according to gender and age. After that, subjects will be randomly assigned to treatment or placebo groups, within each block. Researchers will not inform about the randomization process until completion of data analyses. Allocation concealment will be conducted by application of sealed envelopes containing treatment or placebo, created by a colleague that is not involved with data gathering and participant evaluation (concealment).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a randomized double-blind clinical trial. The synbiotic supplement and its placebo will be packed in the same boxes in terms of appearance (color, shape, smell, weight) and the researcher, patients, evaluators , those responsible for collecting data and data analyzer will not be informed of the contents of the packages until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2020-07-22, 1399/05/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.203

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
symptome of Parkinson's disease (Motor and non motor)
Timepoint
At baseline and after 12 weeks
Method of measurement
Using the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) questionnaire and Calculate the score of the questions and use of them

2

Description
zonulin
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

3

Description
High sensitive C-reactive protein (Hs-CRP)
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

4

Description
TNF-α
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

5

Description
Total antioxidant capacity
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

6

Description
Total oxidant status
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

7

Description
Malodialdehyde
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

8

Description
Glutathione
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

9

Description
Disease stage progression
Timepoint
At baseline and after 12 weeks
Method of measurement
Hoehn and yahr scale

10

Description
Lipopolysaccharid (endotoxin)
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

Secondary outcomes

1

Description
quality of life
Timepoint
at baseline and after 12 week
Method of measurement
Parkinson's Disease Questionnaire - 39

2

Description
dietary intake
Timepoint
at baseline, Week six and twelve
Method of measurement
food record

3

Description
depression and anxiety
Timepoint
At baseline and after 12 weeks
Method of measurement
beck depression questionnaire and hospital anxiety and depression scale

4

Description
Fatigue
Timepoint
At baseline and after 12 weeks
Method of measurement
Fatigue severity scale questionnaire

5

Description
Body mass index
Timepoint
At baseline and after 12 weeks
Method of measurement
It will calculated by weight divided by height (in meters)

6

Description
weight
Timepoint
At baseline and after 12 weeks
Method of measurement
Standard weight scale

Intervention groups

1

Description
Intervention group: They will receive 5 g/d of synbiotic supplement, Containing Lactobacillus, Bifidobacterium and Streptococcus species and Inulin prebiotic(product of Tak gen zist CO,Iran)and Proper diet for parkinson's disease for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: They will receive 5 g/d of maltodextrin and Proper diet for parkinson's disease 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Musa Sadr Clinic in Isfahan
Full name of responsible person
Dr. Fariborz Khorvash neurologist
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjoo Javanmard
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
sanaz mehrabani
Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Major part of information will be available for population.
When the data will become available and for how long
12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable
r_amani@nutr.mui.ac.ir
What processes are involved for a request to access data/document
The data will be sent as soon as possible, after receiving the request
Comments