

# 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 synbiotics 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 patients will not be included 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, Malondialdehyde, 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/li>

sts. 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**

Isfahan

**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- $\alpha$

#### **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 be 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

**Street address**

Foroughi Street

**City**

Isfahan

**Province**

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**Postal code**

8174673461

**Phone**

+98 31 1792 2110

**Email**

Fkhorvash@gmail.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Shaghayegh Haghjoo Javanmard

**Street address**

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**Phone**

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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**

PHD.student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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sanaz\_mehr6500@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Reza Amani  
**Position**  
Professor  
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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences  
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Reza Amani  
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استاد  
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**Other areas of specialty/work**

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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