

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of ingestion of Iranian native multi-strain probiotic Supplement on inflammatory and oxidative stress factors in Parkinson's disease patients

#### Protocol summary

##### Study aim

Effect of ingestion of Iranian native multi-strain probiotic Supplement on inflammatory and oxidative stress factors in Parkinson's disease patients

##### 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. 30 patients with parkinson of eligible in the study will be selected. Patients will be assigned to receive either probiotic supplements and control.

##### Settings and conduct

A total of 30 parkinson patients will be participated in this controlled double-blind trial. Subjects will be received either multispecies probiotic or placebo supplementation daily during a 16 weeks period. Blood samples will be collected from patients at the baseline and end of the study. Fecal microflora, plasma levels of TNF- $\alpha$ , IL-1 $\beta$  and IL-10, serum levels of MDA and TAC are assessed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 and under 80, Diagnosis of idiopathic Parkinson's disease based on UK PD Society Brain Bank criteria, Using l-dopa or dopaminergic agonist. Exclusion criteria: Use antibiotics and commercial probiotics, Major surgery of the GI tract, History of active uncontrolled gastrointestinal disorders or diseases, Age over 80.

##### Intervention groups

Intervention group: : probiotic capsule (Takgene zist,Iran) containing L. rhamnosus, L. plantarum, L. acidophilus, L. salivarius, B. coagulans, B. longum and vitamin D3 (400IU). . Each capsule containing 10 $\times$ 4 cfu/capsule. placebo group:placebo capsule (Takgene zist,Iran) containing magnesium stearate, lactose . Each capsule containing 10 $\times$ 4 cfu/capsule.

##### Main outcome variables

Blood biomarkers including cytokines (TNF- $\alpha$ , IL-1 $\beta$  and IL-10) and oxidative stress (Malondialdehyde (MDA) and

total antioxidant capacity (TAC).

#### General information

##### Reason for update

This clinical trial has a placebo.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200921048793N1**

Registration date: **2020-10-09, 1399/07/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-05-05, 1403/02/16**

Update count: **3**

##### Registration date

2020-10-09, 1399/07/18

##### Registrant information

###### Name

maryam Taj Abadi Ebrahimi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5475 1000

###### Email address

m.tajabadi@iauctb.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of ingestion of Iranian native multi-strain probiotic Supplement on inflammatory and oxidative stress factors in Parkinson's disease patients

**Public title**

Effect of probiotic in Parkinson's disease patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18 and under 80 Diagnosis of idiopathic Parkinson's disease based on UK PD Society Brain Bank criteria Using l-dopa or dopaminergic agonist

**Exclusion criteria:**

Use of systemic antibiotics, antifungals, antivirals or antiparasitics (intravenous, intramuscular, or oral) Use of commercial probiotics: includes tablets, capsules. Major surgery of the GI tract, with the exception of cholecystectomy and appendectomy, in the past five years History of active uncontrolled gastrointestinal disorders or diseases including: inflammatory bowel disease (IBD) including ulcerative colitis (mild-moderate-severe), Crohn's disease (mild-moderate-severe), or indeterminate colitis Infectious gastroenteritis, colitis or gastritis, persistent or chronic diarrhea of unknown etiology, Clostridium difficile infection (recurrent) or Helicobacter pylori infection (untreated) Age over 80

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will occur centrally using an phone randomization system by an independent researcher. There are two treatment arms. Randomization in the mentioned groups will be conducted according to permuted block randomization based on basis of 4 and 6 blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, main investigators, doctors, data collectors and people who evaluate the outcome

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of School of Public Health and Neuroscience Research Center, Shahid Beheshti Univer

**Street address**

School of Public Health and Neuroscience Research Center, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Yaman Ave., Shahid Chamran Exp., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2020-08-19, 1399/05/29

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.136

**Health conditions studied****1****Description of health condition studied**

parkinson

**ICD-10 code**

G20

**ICD-10 code description**

Parkinson's disease

**Primary outcomes****1****Description**

Analyses Level of TNF- $\alpha$ , IL-1 $\beta$ , IL-10, Malondialdehyde (MDA), Total antioxidant capacity (TAC)

**Timepoint**

At the beginning of the study and week 12

**Method of measurement**

ELISA

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: probiotic capsule (Tak Gene Zist, Iran) containing *L. rhamnosus*, *L. plantarum*, *L. acidophilus*, *L. salivarius*, *B. coagulans*, *B. longum*, vitamin D3 (400IU), magnesium stearate, and maltodextrin. Each capsule containing  $4 \times 10^9$  cfu /capsule. 1 capsules per day, Duration 4 months.

#### Category

Treatment - Drugs

### 2

#### Description

Placebo group: Capsule containing magnesium stearate, maltodextrin (Tak Gene Zist, Iran). 1 capsules per day, Duration 4 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Tajrish Hospital

##### Full name of responsible person

Mehri Salari

##### Street address

Shohadaye Tajrish Educational Hospital, Tajrish Square, Tehran Tehran

##### City

Tehran

##### Province

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##### Postal code

1989934148

##### Phone

+98 21 25719

##### Email

mehri.salari@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Neuroscience Research Center, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Yaman Ave., Shahid Chamran Exp., Tehran

##### City

Tehran

##### Province

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##### Postal code

1983963113

##### Phone

+98 21 2242 9768

##### Email

zarghi@sbmu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mehri Salari

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurology

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Maryam Taj Abadi Ebrahimi

##### Position

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Microbiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

shirin hajyani

**Position**

PhD student of Microbiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Microbiology

**Street address**

4th Floor, No 214, East Nosrat St., Towhid Sq

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

patient information in kept confidential and will not be published

**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**

No - There is not 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**

No - There is not a plan to make this available