

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluating the Efficacy of Probiotics in Constipation & Motor Dysfunctions in patients with Idiopathic Parkinson Disease

#### Protocol summary

##### Study aim

Evaluating the effect of probiotics on constipation and movement disorders caused by Parkinson's disease

##### Design

A single center, randomized, blinded controlled trial on 30 patients in two parallel groups.

##### Settings and conduct

Imam Hossein Hospital Neurology Clinic by recording the number of bowel movements, ease of bowel movements, stool consistency, and UPDRS before intervention. At the beginning of the study, the patient will be provided with a booklet to record the number of defecation, ease of defecation, and fecal consistency. At the end of the eight-week study, the booklets will be collected to review and analyze the data. The medicine and placebo will be packed in look-alike box. Researchers include physicians, nurses, outcome assessors, quality control expert, and data analyzers are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Parkinson's Disease and Rome IV criteria for functional constipation - age equal to or >60.  
Exclusion Criteria: Any history of hypersensitivity reaction or contraindications of probiotic use, Active infections, Treated with antibiotics, Immunocompromised patients.

##### Intervention groups

Patients will be divided into intervention and control groups. Both groups will be given brochures, nutritional training, and non-pharmacological strategies. The intervention group will take a capsule containing probiotic and the control group a look-alike placebo capsule.

##### Main outcome variables

Changes in motor/non-motor symptoms of Parkinson's disease, quality of life, number of bowel movements, stool consistency, feeling of complete bowel movement, adverse drug reactions and number of pharmacotherapeutic interventions for constipation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170608034390N11**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

##### Registration date

2022-05-14, 1401/02/24

##### Registrant information

##### Name

Hadi Esmaily

##### Name of organization / entity

SBMU

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

esmaily\_hadi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluating the Efficacy of Probiotics in Constipation & Motor Dysfunctions in patients with Idiopathic Parkinson Disease

**Public title**

Effects of Probiotics on Constipation & Symptoms of Parkinson Disease

**Purpose**

Treatment

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

Patients with Idiopathic Parkinson Disease With Rome IV criteria for functional constipation Age equal to or above 60 years Agreed to sign the informed written consent

**Exclusion criteria:**

There is a contraindication to probiotics, such as previous allergies to it Patients with active infection diagnosis Patients being treated with antibiotics. Patients less than 60 years Patients receiving other probiotics Patients who regularly use laxatives Patients who are immunocompromised Patients who are receiving traditional medicine products to relieve constipation. Patients who are receiving drugs that have a high risk of constipation in the complication profile with a high risk of 10%. (Except for FDA approved drugs in the treatment of Parkinson's)

**Age**

From **60 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**

We will randomly divide the participants into two groups with the same size of 15 participants (30 patients in total), to ensure the equal distribution of patients in the two groups, the block randomization method will be used, and 5 blocks of 6 people in total will be created. Sealed Envelope online software will be used to create random codes. Patients who meet the inclusion criteria receive the code in order and based on the grouping of random blocks, for example, the distribution and coding in the first block is as follows, the first patient Group A, the unique code is ZX6, the second patient Group A, the unique code is GA6, Group B third patient, FR9 code, Group B fourth patient, PP3 code, Group A fifth patient, FR9 code, Group B sixth patient, AE8 code. The number of patients in groups A and B in each block is equal, but the random sequence will be different.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

After preparing the medicine and placebo, they will be packed in the same box by a clinical laboratory expert who is outside the researchers and will be provided with random codes based on the Excel file extracted from the Sealed Envelope software. The package will be transported to the clinic and the codes will remain closed until the statistical analysis is performed.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Research Ethics Committee School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of

**Street address**

Central department of ministry of health and medical education, Simaye Iran st, Shahrak Ghods

**City**

Tehran

**Province**

Tehran

**Postal code**

1467664961

**Approval date**

2022-03-15, 1400/12/24

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1401.011

**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**

Number of defecation per week

**Timepoint**

The beginning of the study and the end of the study

**Method of measurement**

Defecation booklet

## Secondary outcomes

### 1

#### Description

Unified Parkinson's Disease Rating Scale (UPDRS)

#### Timepoint

The beginning of the study and the end of the study

#### Method of measurement

Unified Parkinson's Disease Rating Scale (UPDRS)  
Questionnaire

### 2

#### Description

Defecation consistency

#### Timepoint

The beginning of the study and the end of the study

#### Method of measurement

Bristol stool scale

### 3

#### Description

Sensation of complete evacuation

#### Timepoint

The beginning of the study and the end of the study

#### Method of measurement

Defecation booklet

### 4

#### Description

Frequency of medication interventions to improve constipation

#### Timepoint

The beginning of the study and the end of the study

#### Method of measurement

Defecation booklet

## Intervention groups

### 1

#### Description

The intervention group will take an oral capsule containing probiotics for 8 weeks before going to bed. Both groups will receive nutritional training and non-pharmacological strategies for treating constipation in the form of brochures. The intervention product and placebo will be provided by Fara Daroo Fanavar Mehr Company, with the same packaging, shape, taste and smell.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein Hospital Neurology clinic

##### Full name of responsible person

Nasibeh Ghalandari

##### Street address

Madani Ave., Imam Hossein Sq., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 3000

##### Email

info@ehmc.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

Deputy of Research and Technology, Shahid Beheshti University of Medical Sciences and Health Services, Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 9781

##### 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**

Hadi Esmaily

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Shahid Beheshti University of  
Medical Sciences

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1996835113

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esmaily\_hadi@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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**Latest degree**

Specialist

**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

potentially the whole data will be published after  
participants become unidentified.

**When the data will become available and for how long**

The data will be available 6 months after data publish.

**To whom data/document is available**

Industrial and Academic Researchers

**Under which criteria data/document could be used**

To carry out further research

**From where data/document is obtainable**

Dr. Hadi Esmaily, School of Pharmacy, Shahid Beheshti  
University of Medical Sciences.

**What processes are involved for a request to access data/document**

It will be available through an email to corresponding  
author

**Comments**