Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 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 pharmacotherapic 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
City
Tehran
Province
Tehran
Postal code
1996835113
Phone
+98 21 8887 3704
Email
esmaily_hadi@sbmu.ac.ir

Person responsible for scientific 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, Valiasr ST.
City
Tehran
Province
Tehran
Postal code
1996835113
Phone
+98 21 8887 3704
Email
Esmaily_hadi@sbmu.ac.ir

Person responsible for updating data

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, Valiasr ST.
City
Tehran
Province
Tehran
Postal code
1996835113
Phone
+98 21 8887 3704
Email
Esmaily_hadi@sbmu.ac.ir

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