Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the effect of trehalose on motor and non-motor symptoms of Parkinson disease patients

Protocol summary

Study aim
Investigation of the effect of trehalose on motor and non-motor symptoms of Parkinson disease patients

Design
Triple-blind parallel randomized clinical trial with control group, on 36 patients

Settings and conduct
Patients with Parkinson`s Disease who will refer to private neurology clinic or neurology clinic of Ghaem Hospital, Mashhad, and meet the inclusion criteria, will be enrolled to this study after informed consent. They will be divided randomly into two groups of intervention (trehalose) and control (placebo). The study period will take 3 months. The mentioned outcomes will be assessed and compared between two groups at baseline and after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:Suffering from Parkinson`s disease, Stage 1 or 2 according to Hoehn and Yahr scale, Satisfaction for participation in the research project, Ability to read. The patient can withdraw from the study at any time. Exclusion criteria: Pregnancy, Breastfeeding.

Intervention groups
Intervention group: 10 gr Trehalose for 12 weeks. Control Group: Placebo (succrose) for 12 weeks.

Main outcome variables
Primary Outcomes: Assessment of the disease severity (by UPDRS: Unified Parkinson`s Disease Rating Scale), Assessment of non-motor symptoms (by NMS: non-motor scale), Assessment of quality of life (by PDQ-39: Parkinson`s disease quality of life-39), Serum level of α-Synuclein. Secondary Outcomes: Assessment of the stage of Parkinson`s disease (by Hoehn and Yahr Scale), Assessment of the depression and anxiety (by DASS: Depression and Anxiety Stress Scale), Assessment of the cognition in Parkinson`s Disease (by MMSE: Mini-Mental State Examination), Need to increase the dose or change the previous treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181022041407N10**
Registration date: **2024-08-25, 1403/06/04**
Registration timing: **prospective**

Last update: **2024-08-25, 1403/06/04**
Update count: **0**

Registration date
2024-08-25, 1403/06/04

Registrant information
Name
Maryam Emadzadeh
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-06, 1403/07/15
Expected recruitment end date
2026-04-04, 1405/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigation of the effect of trehalose on motor and non-motor symptoms of Parkinson disease patients

Public title
Investigation of the effect of trehalose on Parkinson disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from Parkinson disease Stage 1 or 2 of Parkinson`s disease (according to Hoen and Yahr scale)
Satisfaction for participation in the research project
Ability to read
Exclusion criteria:
Pregnancy Breastfeeding
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be done using the block sizes of 2 and 4 with randomization websites such as sealedenvelope.com. After randomization, the type of treatment will be written with odds and even numbers (or A/B codes) in separate papers and placed in an opaque envelope or the paper will be wrapped so that no one can see inside the paper (allocation concealment). After obtaining informed consent from the participants, one paper will be taken in order and according to the noted code, the participants will be placed in one of the intervention or placebo groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After randomization, the patients will be placed in two groups of A/B (or odds/even codes) and will received the products similar in shape and color (blinding of participants). The physician who will give the products to participants, received the boxes of the products with randomized codes (so the physician is blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) (blinding of the assessor). Data will be entered to the SPSS software with codes (blinding of the analyzer).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad University of Medical Sciences
Street address
Ghoreshi Building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2024-06-08, 1403/03/19
Ethics committee reference number
IR.MUMS.REC.1403.198

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
Assessment the severity of disease
Timepoint
At baseline and after 3 months
Method of measurement
Using Unified Parkinson's disease rating scale (UPDRS)

2

Description
Assessment of non-motor symptoms
Timepoint
At baseline and after 3 months
Method of measurement
Using non-motor scale (NMS)

3

Description
Quality of life
Timepoint
At baseline and after 3 months

Method of measurement
Using Parkinson`s disease quality of life -39 (PDQ-39)

4

Description
Serum level of α-Synuclein
Timepoint
At baseline and after 3 months
Method of measurement
Blood Test

Secondary outcomes

1

Description
Assessment the stage of Parkinson`s disease
Timepoint
At baseline and after 3 months
Method of measurement
Using Hoehn and Yahr Scale

2

Description
Assessment the depression and anxiety of patients
Timepoint
At baseline and after 3 months
Method of measurement
Using depression anxiety stress scale (DASS)

3

Description
Assessment the cognition in Parkinson`s disease
Timepoint
At baseline and after 3 months
Method of measurement
Mini-Mental State Examination (MMSE)

4

Description
Need to increase the dose or change the previous treatment
Timepoint
After 3 months
Method of measurement
After physical examination of patient and according to the physician`s advice

Intervention groups

1

Description
Intervention group: Trehalose 10 g per day for 12 weeks, made by Shaanxi Fruiterco Biotechnology Co.,Ltd
Category
Treatment - Drugs

2

Description
Control group: Placebo (one sachet of sucrose per day for 12 weeks)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Ghaem Hospital
Full name of responsible person
Ali Shoeibi
Street address
Ghaem Hospital, Ahmad Abad Blvd.
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
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Position
Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

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

Undecided - It is not yet known if there will be a plan to make this available