

Probiotic supplementation with Lactiplantibacillus plantarum OL3246 and quality of life of patients with Parkinson's disease

Submission date 22/06/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/08/2026	Overall study status Completed	☐ Protocol
Last Edited 14/08/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

A randomized, double-blind, placebo-controlled pilot trial evaluating the effect of Lactiplantibacillus plantarum OL3246 on quality of life, depressive symptoms, neurodegenerative and gut–redox biomarkers in patients with Parkinson's disease

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/06/2022, University Bioethics Committee for Scientific Research at the Jerzy Kukuczka Academy of Physical Education in Katowice (Mikołowska 72A, Katowice, 40-065, Poland; +48322075433; komisjabioetyczna@awf.katowice.pl), ref: Resolution No. 6/2022

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Basic science, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Evaluating supplementation effect on quality of life in patients with Parkinson's disease.

Interventions

Permuted-block randomization with a fixed block size of four (2:2 ratio) was generated using a computer algorithm. Both participants and researchers were blinded to the group allocation.

1. Intervention group: capsules, containing Lactiplantibacillus plantarum OL3246 (deposit number: KPD 1760) lyophilizate and excipients (1.4×10^{10} CFU per day; taken orally as a 370mg capsule containing 7×10^9 CFU/capsule twice a day: morning and evening).

2. Placebo group: Placebo capsules contained an equal mass of fulfillment, while the probiotic was substituted by maltodextrin (taken orally as a 370mg capsule twice a day: morning and evening).

The duration of the intervention is 3 months.

Intervention Type

Supplement

Primary outcome(s)

1. Quality of life measured using the Parkinson's Disease Questionnaire (PDQ-39) at pre - baseline (timepoint 0), post - after 3 months

Key secondary outcome(s)

Completion date

15/11/2023

Eligibility

Key inclusion criteria

1. Diagnosed Parkinson's disease according to UK PDS BB
2. Overall good health condition
3. MMSE > 24

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

55 Years

Upper age limit

85 Years

Sex

All

Total final enrolment

36

Key exclusion criteria

1. Diagnosed dementia
2. Diabetes mellitus
3. Clinically active depression (BDI > 26 and positive clinical diagnosis)
4. Substance use disorders or intoxication
5. Uncontrolled hypertension
6. Unstable ischemic heart disease
7. Allergies, particularly severe allergic reactions
8. Other serious medical conditions that, in the investigator's opinion, could interfere with test performance or supplement tolerance
9. Use of psychotropic medications
10. Use of antibiotics and probiotics during past 3 months
11. Major changes in diet in last 3 months

Date of first enrolment

01/06/2023

Date of final enrolment

15/07/2023

Locations

Countries of recruitment

Poland

Sponsor information

Organisation

Olimp Laboratories Sp. z o.o.

Funder(s)

Funder type**Funder Name**

Narodowe Centrum Badań i Rozwoju

Alternative Name(s)

National Centre for Research and Development, The National Centre for Research and Development, Polish National Center for Research and Development, National Center for Research & Development, NCBR, NCBiR, NCRD

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Poland

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available