The Add-On Effect of Lactobacillus plantarum PS128 in Patients With Parkinson's Disease: A Pilot Study

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1. Assessment of Outcomes

In this study, the primary measurements were the Unified Parkinson's Disease Rating Scale part III (UPDRS-III) motor scores and changes in patient's "ON-OFF" diary recordings, and modified Hoehn and Yahr scale (mHYS). The secondary measurements were the 39-item Parkinson's Disease Questionnaire (PDQ-39), Non-Motor Symptoms Scale (NMSS), BDI-II, patient assessment of constipation symptoms (PAC-SYM), Patient Global Impression of Change (PGI-C), and other metabolic profiles. All clinical assessments were performed after 12 h of overnight withdrawal from antiparkinsonian medications (24 h of withdrawal was needed if the participants were taking prolonged release dopaminergic agonists). Therefore, UPDRS-III and mHYS were scored in the OFF state the next morning as well as the metabolic profiles. Then, the medications were self-administered by each patient before the secondary measurements. The UPDRS, mHYS, PDQ-39, NMSS, BDI-II, PAC-SYM, and PGI-C were scored 40–60min later in the patients' best ON state. For safety assessment, physical and neurological examinations were performed to evaluate the overall health of the subjects at weeks 0 and 12. In addition, all subjects were actively monitored for the occurrence of adverse events by telephone at least once per week.

2. Biochemical Measurements

A blood sample of 15mL and a urine sample of 10mL were collected at weeks 0 and 12. The serum high-sensitivity C-reactive protein level was determined by turbidimetric immunoassay. The plasma myeloperoxidase (MPO) and urinary 8-hydroxy-2'-deoxyguanosine were measured by enzyme-linked immunosorbent assay. The plasma glutathione peroxidase and total antioxidant capacity were measured by Ransel test kits (Randox Laboratories Ltd., UK) and ferric-reducing ability, respectively. The urinary creatinine (CRE) level was determined by MeDiPro creatinine test. All procedures were performed according to the manufacturer's

instructions.

3. Statistics Analysis

For this clinical trial, all statistical analyses are conducted using SPSS software (Version 22.0, IBM Corp., Armonk, NY). Descriptive statistics are presented as mean ± standard deviation (SD). The Wilcoxon signed-rank test is used for comparisons on ordinal scales when a significant difference is observed. This test is employed to evaluate changes in total UPDRS, UPDRS-I, UPDRS-II, UPDRS-III, UPDRS-IV, as well as subscores for tremor, rigidity, akinesia, and postural instability gait disorder (PIGD), mHYS, diary recordings, PDQ-39, BDI-II, and PAC-SYM from baseline (V0) to post-intervention (V1, 12 weeks). Effect sizes are calculated using Cohen's d, defined as the mean change divided by the SD. For nominal scale variables with significant differences, the chi-square test is applied, particularly for the NMSS. Paired Student's t-test is used to assess differences in metabolic parameters between baseline and after the probiotics intervention. All data are reported as the mean ± SD, with statistical significance set at $p < 0.05$.