Effects of Lemborexant on Motor-sleep Comorbidity in Parkinson's Disease

NCT07384429

Status	RECRUITING
Phase	Phase 4
Sponsor	YangPan
Enrollment	44 participants

Key Eligibility Criteria

Inclusion (6)

- \. Aged 50 years or older;
- \. Diagnosed with idiopathic Parkinson's disease according to the Movement Disorder Society Clinical Diagnostic Criteria for Parkinson's Disease (2015), with a Hoehn \& Yahr stage of 1 to 4;
- \. Disease duration of e 2 years since diagnosis, clinically stable, and able to comply with the research assessments and interventions;
- \. Diagnosis of insomnia disorder meeting the criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), with an Insomnia Severity Index (ISI) score of e 15;
- \. Stable medication regimen for at least 4 weeks prior to the study;

... and 1 more (see full listing online)

Exclusion (10)

- \. History of or diagnosis with a severe psychiatric disorder, such as depression, anxiety disorders, schizophrenia spectrum disorders, or bipolar disorder;
- \. Presence of a clinically defined neurological disorder (assessed via self-report), including but not limited to: any condition potentially associated with increased intracranial pressure, space-occupying brain lesions, history of stroke, transient ischemic attack within the past 2 years, cerebral aneurysm, dementia, or multiple sclerosis;
- \. Severe cognitive impairment (Mini-Mental State Examination (MMSE) score below 24) or inability to complete questionnaires independently;
- \. Chronic obstructive pulmonary disease (COPD) or any lifelong history of sleep-related breathing disorders, such as sleep apnea;
- \. Excessive daytime sleepiness, defined as self-reported daily daytime napping e 1 hour per day on e 3 days per week;

... and 5 more (see full listing online)

Locations (1 total)

Zhongnan hospital, Wuhan, Hubei, China