

A Phase 2 Study to Assess the Effects of SUL-238 on High Energy Phosphates With ³¹P-MRS in Patients With Early, Untreated Parkinson's Disease

NCT07322887

Status	RECRUITING
Phase	Phase 2
Sponsor	GEN Olaç ve Sağlık Ürünleri A.Ş.
Enrollment	45 participants

Key Eligibility Criteria

Inclusion (13)

- Untreated Parkinson's Disease (PD) patients diagnosed in accordance with the UK PDS Brain Bank Criteria for the diagnosis of PD. Patients must have bradykinesia and at least one of the following:
 - muscular rigidity
 - rest tremor (4-6 Hz)
 - postural instability unrelated to primary visual, cerebellar, vestibular or proprioceptive dysfunction.
 - The duration of PD since diagnosis is \geq 1 year.
- ... and 8 more (see full listing online)

Exclusion (20)

- Atypical parkinsonism, including that due to drugs, metabolic disorders, encephalitis, cerebrovascular disease, normal pressure hydrocephalus, or other neurodegenerative disease.
 - Any history of intellectual disability or psychiatric disorders, including substance use disorders, according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria, except a history of mild depression/anxiety that has been resolved for at least the past 3 months.
 - A positive answer to questions 3 through 5 on the Columbia-Suicide Severity Rating Scale (C-SSRS) at screening.
 - A positive Hepatitis B surface antigen, Hepatitis C antibody, or Human Immunodeficiency Virus (HIV) antibody test at screening.
 - Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) levels greater than 1.5 times the upper limit of normal (ULN) at screening or between screening and first dose administration.
- ... and 15 more (see full listing online)

Locations (1 total)

CTC Netherlands BV, Groningen, Netherlands