

Parkinson's Disease Inclusion/Exclusion Criteria

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Assessment Date

10/27/2020



Inclusion Criteria

1. Male or female age 30 years or older at time of PD diagnosis.

No

Yes

2. A diagnosis of Parkinson disease for 2 years or less at Screening.

No

Yes

3. Not expected to require PD medication within at least 6 months from Baseline.

No

Yes

4. Patients must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia.

No

Yes

6. Individuals taking any of the following drugs: alpha methyl dopa, methylphenidate, amphetamine derivatives or modafinil, must be willing and medically able to hold the medication for at least 5 half-lives before DaTscan imaging.

No

Yes

8. Able to provide informed consent.

No

Yes

9. Women may not be pregnant, lactating or planning pregnancy during the study.

No

Yes

Includes a negative pregnancy test on day of Screening DaTscan imaging test prior to injection of DaTscan.

Exclusion Criteria

1. Currently taking levodopa, dopamine agonists, MAO-B inhibitors (e.g., selegiline, rasagiline), amantadine or another PD medication.

No

Yes

2. Has taken levodopa, dopamine agonists, MAO-B inhibitors or amantadine within 60 days of Baseline visit.

No

Yes

3. Has taken levodopa or dopamine agonists prior to Baseline visit for more than a total of 90 days.

No

Yes

4. Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g. Wilson's disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy).

No

Yes

5. A clinical diagnosis of dementia as determined by the investigator.

No

Yes

6. Previously obtained MRI scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator).

No

Yes

7. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

No

Yes

8. Current treatment with anticoagulants (e.g., coumadin, heparin, oral thrombin inhibitors) that might preclude safe completion of the lumbar puncture.

No

Yes

9. Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or clinically significant coagulopathy or thrombocytopenia.

No

Yes

10. Any other medical or psychiatric condition or lab abnormality, which in the opinion of the investigator might preclude participation.

No

Yes



Neurological Exam

Montreal Cognitive Assessment (MoCA)

