

Parkinson's Disease (LRRK2 or GBA)

Inclusion/Exclusion Criteria

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Assessment Date

11/09/2020



Inclusion Criteria

1. Male or female age 30 years or older at Screening visit.

No

Yes

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

No

Yes

3. 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

4. Hoehn and Yahr stage I or II at Baseline.

No

Yes

5. Confirmation of causative LRRK2 or GBA (willingness to undergo genetic testing as part of genetic screening and be informed of genetic testing results, or documentation of prior genetic testing results).

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

7. Confirmation that participant is eligible based on Screening 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. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine within 6 months of Screening visit.

No

Yes

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

No

Yes

3. 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

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

No

Yes



Determination of Freezing and Falls

MDS-UPDRS Part IB and Part II

