PPMI MNI1008 PET Imaging Substudy

Inclusion/Exclusion Criteria

All inclusion criteria must be marked "Yes" and all exclusion criteria must be marked "No" before proceeding to enrollment. Otherwise, complete "Screen Fail" CRF for this substudy.

A. Assessment Date: __ __ /__ __/ __ __ __ __ (mm/dd/yyyy)

Inclusion Criteria:

1. Able and willing to provide informed consent.

   ○ Yes ○ No

2. Ability and willingness to comply with all study procedures and requirements.

   ○ Yes ○ No

3. Demonstrate adequate circulation to both hands as evidenced by Allen's test or Barbeau test (for safe placement of radial arterial lines)

   ○ Yes ○ No

4. Male or Female (Females must meet additional criteria specified below, as applicable)

   a. Females must be of non-childbearing potential or using a highly effective method of birth control 14 days prior to until at least 24 hours after injection of [18F]MNI1008.

      - Non-childbearing potential is defined as a female who must be either postmenopausal (no menses for at least 12 months prior to PET scan) or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy).
      - Highly effective method of birth control is defined as practicing at least one of the following: A birth control method that results in a less than 1% per year failure rate when used consistently and correctly, such as oral contraceptives for at least 3 months prior to injection, an intrauterine device (IUD) for at least 2 months prior to injection, or barrier methods, e.g., diaphragm or combination condom and spermicide. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) is not acceptable.

   b. Females of childbearing potential must not be pregnant, breastfeeding or lactating, or planning pregnancy during the duration of the study.

   ○ Yes ○ No

Inclusion Criteria – Healthy Control only:

5. Enrolled in the PPMI 002 Clinical study as a healthy control participant

   ○ Yes ○ No

6. Any gender aged 50 to 75 years of age

   ○ Yes ○ No

7. Negative CSF α-synuclein seed amplification assay (α-syn SAA)

   ○ Yes ○ No

8. Movement Disorders Society- Unified Parkinson's Disease Rating Scale Part III (MDS-UPDRS III) score of <6 at the last PPMI 002 annual visit

   ○ Yes ○ No

9. Cognitively intact with Montreal Cognitive Assessment (MoCA) ≥26 at the last PPMI 002 annual visit

   ○ Yes ○ No

Inclusion Criteria – Parkinson's Disease and Prodromal only:

10. Enrolled in the PPMI 002 Clinical study as a Parkinson's disease (PD) participant or a Prodromal PD participant

    ○ Yes ○ No

11. Any gender aged 50 to 80 years of age

    ○ Yes ○ No

12. Positive CSF α-syn SAA

    ○ Yes ○ No

13. Montreal Cognitive Assessment (MoCA) ≥24 at the last PPMI 002 annual visit

    ○ Yes ○ No

Exclusion Criteria:

1. Clinical evidence of other non-synucleinopathy neurodegenerative diseases, such as Alzheimer's disease

   ○ No ○ Yes

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

   ○ No ○ Yes

3. Received any of the following drugs: dopamine receptor blockers (neuroleptics), metoclopramide and reserpine, within 6 months of Baseline Visit.

   ○ No ○ Yes

4. Any structural abnormality or finding on MRI Brain previously acquired since onset of motor symptoms or obtained at screening, suggestive of clinically significant neurological disorders other than the diseases of interest (in the opinion of the investigator).

   ○ No ○ Yes

5. Currently being treated with and unable to hold antiplatelets (other than low dose aspirin up to 100mg/day) or anticoagulants that might preclude safe attempt of a lumbar puncture, if applicable.

   ○ No ○ Yes

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

   ○ No ○ Yes

7. Any other reason that in the opinion of the investigator, including abnormal labs, that could interfere with the safety with radiotracer injection, would render the participant unsuitable for the study enrollment.

   ○ No ○ Yes

8. Conditions or medications that preclude safe performance of imaging procedures (e.g., MRI or DaTscan), including severe claustrophobia, MRI-incompatible metal implants, or hypersensitivity to imaging agents.

   ○ No ○ Yes

9. Known hypersensitivity to DaTscan or iodine-containing compounds. Participants with iodine sensitivity may be evaluated to proceed with imaging without iodine premedication at the investigator's discretion.

   ○ No ○ Yes

10. Use of medications known to interfere with DaTscan imaging (e.g., bupropion, amphetamines, methylphenidate, modafinil, alpha-methyldopa), unless the participant is willing and medically able to discontinue the medication for at least 5 half-lives or for specified duration per investigator's judgement prior to imaging.

    ○ No ○ Yes

11. Contraindications to arterial line placement, including but not limited to a history of bleeding disorders, recent significant blood donation, or inability to safely hold anticoagulant or antiplatelet medications, as determined by the investigator.

    ○ No ○ Yes