18F-mFBG Cardiac Uptake With Lewy Body Dementia

NCT07176286

Status	RECRUITING
Phase	Phase 2
Sponsor	Innervate Radiopharmaceuticals LLC (Formerly: Illumina Radiopharmaceuticals LLC)
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (7)

- \. e18years of age at study entry. 2. Able and willing to comply with study procedures and signed and dated informed consent is obtained.
- \. A male or a female who is either surgically sterile (has had a documented bilateral oophorectomy and/or hysterectomy), postmenopausal (cessation of menses for more than 1 year), non-lactating, or of childbearing potential for whom the result of a serum pregnancy test performed at screening is negative.
- \. All subjects: Judged clinically stable for at least 30 days before enrolment into the study and remains stable to the time of the study imaging procedure.
- For Lewy body disease subjects (Study Cohort I):
- \. The subject has a diagnosis of either PD or DLB based on accepted clinical criteria at least 6 months before enrollment into the study.

... and 2 more (see full listing online)

Exclusion (8)

- \. Previously entered into this study or has participated in any other investigational product or medical device study within 30 days of enrollment.
- \. History or suspicion of significant allergic reaction or anaphylaxis to any components of the 18F-mFBG imaging agent.
- \. Presents with any other clinically active, serious, life-threatening disease with a life expectancy of less than 1 year or where participation in the study might compromise the management of the subject or other reason that in the judgment of the investigator(s) makes the subject unsuitable for participation in the study.
- \. Documented ischemic heart disease (prior myocardial infarction, unstable angina, etc) or a diagnosis of heart failure of ischemic or non-ischemic etiology.
- \. Serious non-cardiac medical condition associated with significant elevation of plasma catecholamines including pheochromocytoma.

... and 3 more (see full listing online)

Locations (1 total)

Houston Methodist Neurological Institute, Houston, Texas, United States