Elucidating the Role of Cholinergic Degeneration in Cognitive Fluctuations in Lewy Body Dementia

Status: RECRUITING

Eligibility Criteria

Age: 50 years to 89 years old

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Arm 1: * Age range: 50 ≤ age \< 90. * Diagnosis of dementia with Lewy bodies (DLB), Parkinson disease dementia (PDD), Parkinson disease with Mild Cognitive Impairment (PD-MCI), Mild Cognitive Impairment with Lewy bodies (MCI-LB). * DLB participants must fulfill criteria for clinically probable DLB based on the 2017 4th consensus report of the DLB consortium. * PDD participants must meet criteria for clinically probable PD according to the MDS Clinical Diagnostic Criteria for Parkinson's Disease and must also meet criteria for probable PDD based on the 2007 Movement Disorders Society clinical diagnostic criteria. * PD-MCI participants must meet criteria for clinically probable PD according to the MDS Clinical Diagnostic Criteria for Parkinson's Disease and meet criteria for Mild Cognitive Impairment on cognitive testing at screening. * MCI-LB participants with must meet established research criteria. * Capacity to provide informed consent or, if unable, availability of a legally authorized representative or guardian who can provide informed consent. * Availability of informant (for participants meeting criteria for dementia). * Ability and willingness to comply with the study-related procedures. * Fluent in spoken and written English (due to cognitive testing)

Exclusion Criteria:

Arm 1 * History of cognitive disorder or psychiatric disorder other than that related to dementia with Lewy bodies or Parkinson disease dementia. * History of deep brain stimulation or any neurosurgical procedure. * History of structural brain disease or known significant cerebrovascular disease. * History of seizures or epilepsy and/or use of sodium channel blockers, i.e. carbamazepine, oxcarbazepine, phenytoin, topiramate, lamotrigine, felbamate, zonisamide, rufinamide, lacosamide, eslicarbazepine, and valproate. * Greater than two alcoholic drinks per day for men and one per day for women. * Regular use of benzodiazepines or barbiturates. (If benzodiazepines are taken as needed only, these medications cannot be taken within 5 half-lives of screening visit or between screening visit and EEG.) * Severe dementia (based on PI assessment of subject dependence level for instrumental activities of daily living) * Any contraindication to brain MRI. * Any medical condition that would interfere with ability to complete all study procedures. * Participants must not be pregnant, planning to become pregnant, or father a child for the duration of the study

Inclusion Criteria:

Arm 2 (Cholinesterase inhibitor cohort) inclusion criteria: * Completed Aim 1. * Clinical diagnosis of LBD (DLB or PDD) with CF. * Not taking a cholinesterase inhibitor and has not taken a cholinesterase inhibitor in the previous 90 days. * Ability and willingness to comply with the ChEI Cohort procedures (including galantamine administration), or a caregiver willing and able to ensure compliance.

Exclusion Criteria:

Arm 2 (Cholinesterase inhibitor cohort) exclusion criteria: * Severe hepatic impairment. * Renal failure. * Significant bradycardia (\<50 bpm) at screening or history of AV block. * Any contraindication to galantamine administration based on PI discretion. Inclusion criteria: Arm 3 (Healthy Controls) * Age range: 50 ≤ age \< 90. * Healthy controls should not have any known neurologic conditions that could interfere with study procedures or results. * Capacity to provide informed consent or, if unable, availability of a legally authorized representative or guardian who can provide informed consent. * Availability of informant (for participants meeting criteria for dementia). * Ability and willingness to comply with the study-related procedures. * Fluent in spoken and written English (due to cognitive testing).

Exclusion Criteria:

Arm 3 (Healthy Controls) * No History of cognitive disorder or psychiatric disorder other than that related to dementia with Lewy bodies or Parkinson disease dementia. * No History of deep brain stimulation or any neurosurgical procedure. * No History of structural brain disease or known significant cerebrovascular disease. * No History of seizures or epilepsy and/or use of sodium channel blockers, i.e. carbamazepine, oxcarbazepine, phenytoin, topiramate, lamotrigine, felbamate, zonisamide, rufinamide, lacosamide, eslicarbazepine, and valproate. * Any medical condition that would interfere with ability to complete all study procedures. * Participants must not be pregnant, planning to become pregnant, or father a child for the duration of the study

Conditions & Interventions

Interventions:
PROCEDURE: Syn-One skin biopsy, DIAGNOSTIC_TEST: Multi modal MRI, DIAGNOSTIC_TEST: Assessment of dynamic EEG features over 48-hour periods across all study aims, DIAGNOSTIC_TEST: Plasma biomarkers, DRUG: Galantamine HBr extended-release 8mg capsules (8mg ER).
Conditions:
Dementia With Lewy Bodies, Parkinson Disease Dementia, Healthy Controls
Keywords:
Parkinson Disease with Mild Cognitive Impairment, Mild Cognitive Impairment with Lewy Bodies

More Information

Contact(s): Madison Clemons - Madison.Clemons@vcuhealth.org
Principal Investigator:
IRB
Number:
System ID: NCT07284290
