For more information about this research study, please contact:

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RewinD-LB

Has a health care professional said that you or your loved one may have

Dementia with Lewy Bodies (DLB)

The RewinD-LB study is evaluating an investigational medication for people with DLB. Please read this brochure to learn more about this opportunity.

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Dementia with Lewy bodies (DLB) is a disease associated with abnormal deposits of protein in the brain. These deposits are called Lewy bodies. Lewy bodies affect chemicals in the brain that can lead to problems with thinking, movement, behavior, and mood.

DLB is characterized by progressive dementia, and fluctuating problems with memory and attention. Sleep disturbances, hallucinations, as well as tremors and problems with movement (called Parkinsonism) are also common symptoms. Managing this disease can be difficult and disruptive for both people with DLB and their caregivers.

There is no currently approved medication that targets the underlying cause and process of DLB. Only symptomatic treatments are available for Parkinsonian symptoms. This is why medical researchers look for new and, hopefully, better treatments for individuals with DLB.

Before new medications can be approved for public use, they must be tested in research studies like this one. If you or a loved one has probable DLB, please consider participating in this study.

Study Overview

In this research study we will evaluate neflamapimod to see if it can improve learning skills, problem solving skills, and memory loss in people with DLB. Neflamapimod is investigational because it has not yet been approved by medical authorities.

Treatment Period
Participants will complete a Screening Visit to find out if they qualify for the study. Participants who pass screening will be assigned to take a neflamapimod capsule or a placebo capsule. Both capsules will look the same, but the placebo has no active ingredients. The assignment is made randomly like flipping a coin.

The assigned treatment will be taken 3 times a day for 16 weeks (4 months). During the treatment period, participants will visit the study center for tests and exams 6 times and one additional time after the treatment period ends.

Extension
All study participants who complete the initial 16-week period of the study will be able to continue in the study and receive neflamapimod for an additional 32 weeks (8 months), regardless of whether they received neflamapimod or placebo during the first 16 weeks. The extension study will involve an additional 5 study center visits.

Participation Requirements

To join this study, potential study participants must:

- be 55 years of age or above
- have probable dementia with Lewy bodies (DLB)
- must have a reliable caregiver who can come to study center visits and help with study procedures and evaluations

This is not a complete list of study requirements. The staff at the study center will explain the complete list of requirements.

Costs and Expenses

There is no cost to participate. Participants do not pay for the study drug, clinic visits, or study-related medical procedures or tests. Participants who satisfy applicable requirements may be compensated for study-related time and expenses. Please ask the study staff for details.

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