Brief Description of the RVT-102-2002 Study for Website

Nelotanserin for Potential Treatment of REM Sleep Behavior Disorder in DLB and PDD

An estimated 80% of people with dementia with Lewy bodies (DLB) and 60% of people with Parkinson's disease experience REM sleep behavior disorder (RBD), a serious condition where a person physically and/or vocally acts out their dreams. A clinical study is now evaluating nelotanserin, an investigational medication, as a treatment for RBD in people with DLB or Parkinson's disease dementia (PDD). Learn more about local participation here. [insert website link and/or phone number]

RVT-102-2002 Study Longform Description for Website

Nelotanserin for Potential Treatment of REM Sleep Behavior Disorder in DLB and PDD

What is REM Sleep Behavior Disorder?

REM sleep behavior disorder (RBD) is a condition in which a person appears to act out their dreams. It may include talking in one's sleep, violent movements, or falling out of bed. An estimated 80% percent of people with dementia with Lewy bodies (DLB) and 60% of people with Parkinson's disease experience RBD. Unfortunately, while sleep disorders are common in those with DLB or Parkinson's disease dementia (PDD), they are often under-diagnosed. RBD can cause injury to the person or their bedpartner as they physically act out their dreams.

What is this study about?

This trial is testing an experimental drug, called nelotanserin, to determine its effectiveness in treating RBD in people with DLB or PDD.

What is involved?

Each participant will attend an initial screening visit plus 4 additional study visits over the course of approximately 10 weeks. During these visits, participants and their caregivers will complete study assessments and questionnaires. Two of the visits (2-3 nights each) will be conducted at a sleep lab, in which the study team will monitor the participant's sleep patterns and behaviors. The study doctor will also evaluate and monitor participants for safety. Study-related care is provided at no cost, and transportation assistance to and from study visits may be available.

The study is "double-blind, placebo controlled," meaning neither the researcher nor the person in the trial will know who is getting the study drug or a placebo (a study drug look-alike without any active study ingredients).

Participants who complete the study will be eligible for an open-label extension in which all participants will receive nelotanserin.

Who can participate?

An individual may be able to take part in the trial if he/she:

- Is at least 50 years of age

- Has been diagnosed with dementia with Lewy bodies (DLB) or Parkinson's disease dementia (PDD)
- Experiences frequent REM sleep behavior episodes (physically and/or vocally acting out dreams during sleep)

Find a Study Site

To find the study site closest to you or to learn more about this trial please call [insert phone number]

Study Sponsor:

Axovant Sciences