

Are there any risks to participating in this study?

There may be potential risks to participating in this study. All drugs and medical procedures carry a risk of side effects; therefore, it is possible that participants may experience some discomfort or other reactions from use of the study drug. If you decide to participate, the study staff will explain the potential risks to you before any study procedures are conducted.

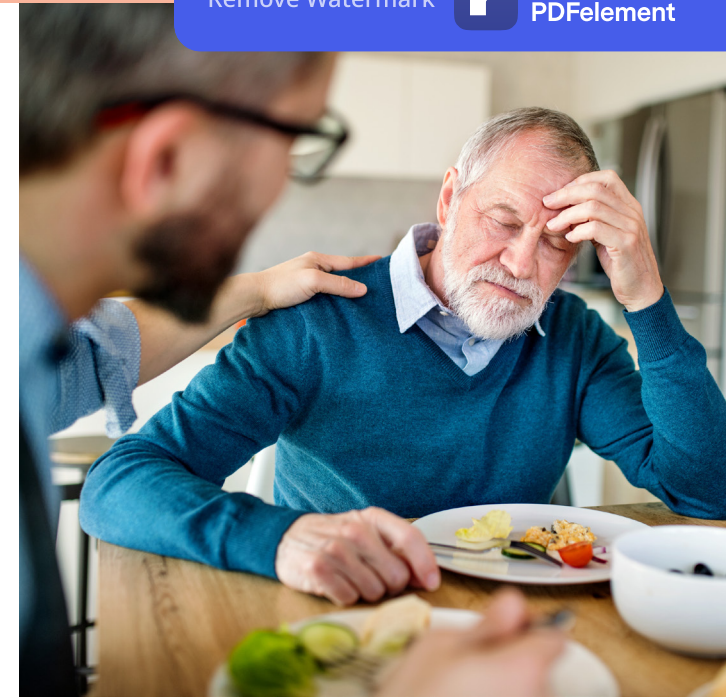
What are the potential benefits of participating?

Participants may or may not receive any benefit from being in this study. It is possible that participants may get better, stay the same, or get worse. In the future, other people with mild cognitive impairment or mild dementia associated with Parkinson's disease or prodromal or manifest Lewy body dementia may be helped by this research.

What are the next steps?

If you or your loved one wish to take the next step toward possible participation or if you have more questions, please contact us as directed on the back of this brochure. Contacting us does not obligate you to participate in this study.

For more information about this clinical research study, please contact:



Are thinking and memory problems adding to your challenge of dealing with

Parkinson's disease or Lewy body disorder?

If so, participating in our clinical research study of an investigational drug for people with mild cognitive impairment may be a good option for you or a loved one.



We understand that living with Parkinson's disease or Lewy body disorder is a daily challenge. In addition to the physical difficulties of the disease, problems with thinking and memory are often present.

These thinking and memory problems, called mild cognitive impairment, affect 15% to 25% of newly diagnosed Parkinson's patients. This impairment has been associated with increased disability and can negatively affect quality of life.

People with mild cognitive impairment associated with Parkinson's disease (MCI-PD) are six times more likely to develop dementia. It is very important to us to conduct clinical research studies with the goal of finding additional treatment options. This is the reason we are conducting this clinical research study.

If you have mild cognitive impairment associated with Parkinson's disease or related Lewy body disorder, or are close with someone who does, please read these answers to commonly asked questions about this study.

What is being researched in this study?

This study seeks to evaluate the safety, tolerability, and effect of a drug called NYX-458 (the "investigational drug") in people who have mild cognitive impairment or mild dementia associated with Parkinson's disease or dementia with Lewy bodies. We are also conducting research into whether it can help with thinking and memory problems.



Who can participate in this study?

To qualify for this study, potential study participants must meet the following criteria:

- Be 50 to 85 years of age with Parkinson's disease or a related Lewy body disorder
- Have a study partner* willing to assist during the study
- Have symptoms of mild cognitive impairment, such as:
 - difficulties with problem solving or paying attention
 - slowed thinking
 - issues with short-term memory

*The study partner is someone who has frequent contact with the study participant and is willing and able to provide information about the participant and attend some study visits.

There are additional requirements to participate. The staff at the study center will explain the complete list of requirements.

What will happen during this study?

At the first visit, the study doctor's staff will give a detailed explanation of this study and its potential risks and benefits. This explanation will be made verbally and in writing. Only after obtaining written consent from the potential participant will study-specific procedures take place. The study partner must also attend this first visit and give written consent to participate.

Next, the study doctor and the doctor's staff will conduct a series of study-related examinations and tests to see if the participant satisfies the requirements to enroll in this study. The study staff will schedule a second screening visit for those participants who satisfy the initial screening requirements. The second screening visit will be at least one week after the first and further tests will be conducted. These two visits comprise the total screening period for participation in this study, and this screening period will last between 14 and 28 days.

Participants who remain qualified after the second visit will be asked to return to begin the treatment period of the study. Qualified study participants will then be randomly assigned into either a placebo group or a dosing group of the study drug. A placebo is a substance that looks like the study drug but has no active ingredients. Neither participants nor study personnel will know which assignment has been made.

Study participants will take the study drug or placebo once daily for 12 weeks. During these 12 weeks, there will be 4 visits to the study center and 3 phone calls with the study doctor's staff. At these visits, study personnel will continue to examine participants and perform various cognitive and safety assessments. Approximately two weeks after the last dose, participants will return for a final follow-up visit.

At all in-person visits during the treatment period, the study staff will ask the participant's designated study partner to answer questions related to the participant's cognitive function. The study partner must attend the first visit of the treatment period to answer these cognitive questions but may answer these questions by telephone if unable to attend subsequent visits.

This study will involve approximately 100 participants.

How long will the study last?

Complete participation in this study will last between 16 and 18 weeks. It will involve seven visits to the study doctor's office and three scheduled phone calls with the study doctor's staff.

Does it cost anything to participate?

There is no cost to participate. Qualified participants receive the investigational drug or placebo and required study-related medical assessments and examinations at no cost. Compensation for time and travel expenses incurred as a result of study participation may also be available.