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What is a clinical research study?

A clinical research study is a carefully designed scientific evaluation of an investigational drug conducted by doctors. Clinical research studies help to answer important medical questions, such as how a new drug acts in the body, how it affects certain diseases or conditions, and whether or not it is safe for wider use. Because clinical studies are voluntary, participants are free to leave the study at any time for any reason.

Why are clinical research studies important?

Clinical studies are the only way new medications for diseases can become approved for widespread public use. They provide a way to test drugs so we will know if they are safe and effective. People who participate in clinical studies contribute to research that will further the knowledge about the treatment of diseases.

Find out more about our new Parkinson's study.

If you've had Parkinson's Disease for 3 or more years, are on levodopa and at least one other PD medication, and you experience periods when your medication wears off, then you might be eligible for this clinical study. The TOZ-PD Study is now enrolling adults 30 to 80 years of age to participate.

For more information, or if you would like to be considered for participation, please contact us at [xxx-xxxx]. We will be available to discuss any concerns or answer any questions.

Site contact information:

Name:

Address:

Telephone:

TOZ-PD STUDY

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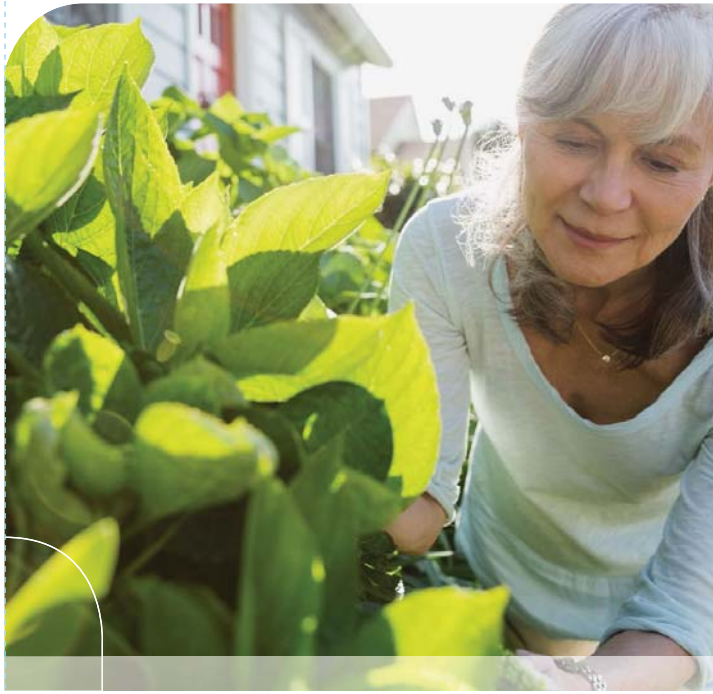

If you have Parkinson's Disease, you may be interested in our clinical research study.

The TOZ-PD Study is looking for people with Parkinson's Disease to participate in a clinical research trial.

Find out more inside.

TOZ-PD STUDY

What Is Parkinson's Disease?

Parkinson's Disease (PD) is caused by the lack of dopamine produced in the brain. Dopamine sends information to the parts of the brain that control movement and coordination. Symptoms of PD such as shaking, muscle stiffness, and slowed movement occur when the brain produces lower than normal levels of dopamine. The most commonly used drug in the treatment of PD is levodopa (L-dopa), but it doesn't always control PD symptoms on its own. Frequently, L-dopa is combined with other medications to keep PD symptoms under control, but after time, they can begin to lose their effect.

What Is the TOZ-PD Study?

The TOZ-PD Study is for people with Parkinson's Disease who are currently taking L-dopa and at least one other medication to control their Parkinson's symptoms. The purpose of the study is to examine the safety and effectiveness of L-dopa in combination with a new investigational medication called tozadenant. Tozadenant acts on the part of the brain where dopamine controls movement.

Approximately 450 people with PD will participate in this study. The study will take place at roughly 80 different research sites in North America and Europe. The entire study will last a total of 86 weeks and require about 14 visits to your study doctor.

People who participate in clinical studies contribute to research that will further the knowledge about the treatment of diseases.

Who can participate in the TOZ-PD Study?

You may be eligible to participate in the study if:

- You are 30 to 80 years old
- It has been at least 3 years since you were diagnosed with PD
- You take L-dopa every day, as well as at least one other anti-PD medication
- You are currently experiencing periods when medication no longer has effects and no longer improves your slowness, mobility, and stiffness

Please be aware that this is only a partial list of requirements. A complete list of requirements will be reviewed with you by a study representative prior to enrollment. Only the study doctor can determine if you are eligible to participate.

How is the study organized?

The TOZ-PD Study is divided into two parts. Part A will test the effect of tozadenant compared to a placebo over a six month time period. A placebo looks exactly like the medication being tested, but contains no active drug. During this part of the study, you will receive either tozadenant 60 mg, tozadenant 120 mg, or a placebo two times daily. Part A of the study evaluates the effects of the study drug. To evaluate the drug, you will be asked to maintain a home diary of when your medication is providing benefit, or when it has worn off. During this part of the study, neither you nor your study doctor will know if you are receiving tozadenant or placebo.

Following Part A, subjects will continue into Part B and receive tozadenant for one year during which more safety data will be collected.

What can I expect to happen during the study?

During Part A and Part B of the study, a number of assessments and procedures will be conducted during each visit to monitor your condition and evaluate how the treatment is working. Assessments include filling out questionnaires and answering questions about your health, medications, side effects, and mood. Procedures such as blood draws, urine sample collection, and ECG readings of your heart rhythm will also be conducted at some or all of your visits.

During Part A, your study doctor or staff will train you on how to complete your diary over a three day period when you are at home. These diaries will be completed prior to each visit.

Remember, your participation in this research is voluntary and you may choose to leave the study at any time, for any reason.