Learn more about the NILO-PD study

Visit our websites:

www.nilopd.org

https://clinicaltrials.gov/ct2/show/NCT03205488

https://foxtrialfinder.michaeljfox.org/

Contact your local study staff:

Study Doctor:
[Insert Site PI's Name]

Study Coordinator:
[Insert Coordinator's Name]
Phone: [Insert Phone #]
Email: [Insert e-mail address]

(Mon – Fri 9am-5pm)

Site Address:
[Insert Site Address]

[Insert Site Logo if applicable]

Thank you for considering this important research study!

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About the Parkinson's Study Group

The Parkinson's Study Group (PSG) is a non-profit group of physicians and other health care providers from medical centers in the United States and Canada, experienced in the care of Parkinson's patients and dedicated to clinical research of Parkinson's Disease (PD). PSG aims to advance knowledge about the causes, disease progression and treatment of PD and related disorders.

PSG is committed to:

- Open communication within the scientific community
- Ensuring research is fully reviewed by other health care providers prior to publication to make certain that all research results (good and bad) are available to the public
- Revealing all potential conflicts of interest of the group and each PSG member, and
- Democratic governance of its organizations and activities.

About clinical trials

What is a clinical trial?

A clinical trial is a study to evaluate promising experimental treatments. They are designed to learn if new medications are safe, tolerable and effective.

NILO-PD

A study of nilotinib in people with Parkinson's disease

Tanya Simuni, MD
Principal Investigator

A clinical trial conducted by the PSG and funded by the Michael J. Fox Foundation for Parkinson's Research

PSG
PARKINSON STUDY GROUP

THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

What is the NILO-PD study?

The NILO-PD study will investigate the safety and tolerability of nilotinib. The Parkinson Study Group (PSG) is conducting this clinical trial in approximately 25 research institutions across the United States. We will enroll **75 participants.**

This study is funded by The Michael J. Fox Foundation for Parkinson's Research.

What is nilotinib?

Nilotinib is a drug approved by the U.S (FDA) to treat certain types of leukemia. It is considered an investigational drug in NILO-PD because it is not approved to treat Parkinson's Disease.

Nilotinib inhibits the activity of a protein linked to pathways associated with PD, and preliminary data from a small Phase I clinical trial evaluating the safety and tolerability of nilotinib in Parkinson's showed potential benefit.

Will everyone receive nilotinib?

It is important that you know this is a placebo controlled study and one-third of the participants will receive a placebo. While the remaining two thirds of participants will receive nilotinib. A placebo is an inactive pill and is often used in research studies to determine whether or not the active study drug is effective.

How long will I be in the study?

Your involvement with the study will last approximately 8.5 — 9months.

What are the risks of nilotinib?

Nilotinib can cause an irregular heartbeat called QT prolongation which can lead to sudden death but your doctor will monitor you heart rate closely. Fever, nausea, cough, headache and tiredness are a few other side effects. Please ask the study doctor about other possible side effects.

What are the benefits to me if I decide to participate in NILO-PD?

Currently, the benefits to you are unknown, but nilotinib may help to normalize the function of the pathways in the brain and reduce alpha-synuclein from collecting, potentially helping to relieve PD symptoms. While there may be no direct benefit to you from participating in the NILO-PD study, you may be contributing to the growing knowledge about PD.

Will I be reimbursed for my participation?

You will receive study drug and procedures at no cost.

Am I eligible to participate?

Participants must meet certain criteria.
Some are:
— You must be between the ages of 40 and 79
— You must have been diagnosed with Parkinson's disease (PD) for more than 5 years
— You need to be on a stable regimen of PD medications that includes levodopa for at least 30 days prior to screening visit

What will I need to do during the study?

— Nilotinib is a capsule that will be taken orally on a daily basis.
— The study will include 11 in person study visits.
— Clinical assessments and questionnaires will be completed
— Several blood samples will be collected throughout the study
— Certain visits will require a Lumbar Puncture (LP)

What is a Lumbar Puncture?

An outpatient procedure where a small needle is inserted between the vertebrae of the lower back at a level below the spinal cord to obtain a small amount of spinal fluid. You may feel some discomfort. First, during the administration of an anesthetic, you may feel a few seconds of stinging or burning when it is injected. Second, you will feel a pressure sensation when the needle is inserted, and there is usually some brief pain when the needle goes through the tissue surrounding the spinal cord. Overall, discomfort throughout the entire procedure is minimal to moderate.

How can I get more information about the NILO-PD study?

If you are interested in participating or want to learn more about this study, please contact:

[NAME]
Phone: [INSERT Phone #].
Email: [Insert Email]

Thank you for your interest in the NILO-PD study and your commitment to accelerating Parkinson's disease research.