

ADVANCING PARKINSON'S TREATMENT BEGINS WITH YOU

Find out how you or a loved one can make a difference by participating in a clinical trial today.

About the Trial

Almost all drugs currently used to help people with Parkinson's disease (PD) work by increasing the activity of a chemical in the brain called dopamine. While drugs working in this manner, which includes levodopa, have provided tremendous benefit to patients, none of them slow disease progression. Furthermore, levodopa's effects wane over time, which creates the need to increase the dose. When levodopa is used at too high a dose or over too long a time, it causes the trembling side effects people with PD experience.

Scientists have known for a long time that Parkinson's symptoms arise when both low dopamine levels in the brain and neuroinflammation (and the associated insulin resistance) occur at the same time.

The trial drug, NE-3107, is a new molecule with a unique mechanism of action that is believed to have the potential to interrupt both inflammation and insulin resistance in the brain. In animal studies, the trial drug showed that the reduction of neuroinflammation and insulin resistance led to improved movement, a decrease in the levodopa side effects, as well as a decrease in the loss of brain cells, which means it has the potential to slow disease progression. This clinical trial will test whether NE-3107's benefits for PD seen in animal studies translate to benefits in people.

Who Qualifies to Participate?

- Adults at least 30 years of age
- Those with a diagnosis of Parkinson's disease and on a stable PD medication for at least 4 weeks
- Carbidopa/levodopa dose of at least 300 mg daily, distributed over a minimum of 3 dosing intervals during waking hours
- Those in otherwise generally good health

Additional study criteria apply.



Is This Trial Right For You?

Trial NM201 isn't for everyone. Half of the people in the study will get placebo, and there's no way to know what you got. In order to measure the drug's ability to help with motion, patients on the study will have to withhold their PD medications for at least 8 hours, so that they can be in an "off-state", which can be very uncomfortable. And in order to measure how well NE-3107 works with levodopa when levodopa is wearing off, patients must have advanced enough disease to need to take levodopa 3 times a day. There also may be unknown or unexpected adverse effects or side effects from the drug.

This will take a special person, but the potential reward is a revolutionary change in PD therapy. There can be no guarantee that what we have seen in the laboratory will carry-over to humans, but this question is why we are compelled to conduct this study. If this treatment is proven to be safe and efficacious in clinical trials like this one, your contribution will have helped to change the future of everyone with Parkinson's.

What Does Participation Involve?

After qualifying medical exams there will be 5 visits to the clinic to measure baseline activity of PD meds compared to the activity of only NE-3107 in their systems. Patients participating in the study will need to withhold PD meds from midnight to about 8 AM for 3 days in a row at the beginning of the study, and then again on days 14 and 28, the last day of taking study medications. There is also a safety exam on day 35. Blood samples will be collected at every visit to measure drug concentrations. Except when creating the off-state, everyone will be able to keep taking levodopa during the study.

Potential Side Effects

In completed clinical studies of NE-3107, when NE-3107 was compared to placebo, the most commonly observed event has been headache (11%) versus placebo (10%). Other possible side effects may include increases in blood glucose levels or cholesterol levels, and decreases in blood calcium levels or blood sodium levels. This is not a full listing of all possible observed events. For a full list of side effects, talk with your physician or reference the informed consent.

Be part of potentially life-changing research
and find out how to get involved **today**.

 [BIOVIEPHARMA.COM](https://www.bioviepharma.com)