

Parkinson's Disease (PD)

A study to compare prasinezumab with a placebo in people with early-stage Parkinson's disease who are taking levodopa to manage their disease symptoms

A Study to Evaluate the Efficacy and Safety of Intravenous (IV) Prasinezumab in Participants With Early-Stage Parkinson's Disease

Trial Status
Recruiting

Trial Runs In
2 Countries

Trial Identifier
NCT07174310 2025-522683-32-00
BN44715

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Intravenous Prasinezumab in Participants With Early-Stage Parkinson's Disease

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety, and pharmacokinetics (PK) of prasinezumab compared with placebo in participants with early-stage Parkinson's disease (PD) on stable symptomatic monotherapy with levodopa.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#50 Years & # 85 Years

Healthy Volunteers
No

1. Why is this study needed?

Parkinson's disease (PD) is a long-term condition that gets worse over time. In PD, a naturally occurring protein called alpha-synuclein does not form properly. It sticks together

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to form clumps. This damages nerve cells in certain areas of the brain and causes nerve cells to die. Some of these nerve cells are responsible for the production of a chemical called 'dopamine', which is important for controlling movement. The damage to nerve cells leads to a lack of dopamine in the brain causing movement-related (motor) and non-motor symptoms. Current treatments relieve symptoms but do not reverse, slow down or stop brain cells from dying. Medicines that replace dopamine are mainly used. As the disease gets worse, these medicines become less effective at controlling symptoms. New medicines are needed that can prevent brain cell death to stop or slow the speed at which PD gets worse.

This study is testing a medicine called prasinezumab. It is being developed to slow down the progression of PD symptoms. Prasinezumab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved prasinezumab for the treatment of PD. This study aims to compare the effects of prasinezumab against non-active medicine (placebo) in people with PD who are taking levodopa to manage their symptoms.

2. Who can take part in the study?

People of 50 to 85 years of age with early-stage PD (that does not affect their balance) can take part in the study if they are being treated with stable doses of levodopa for at least 3 months and have been diagnosed with PD within the last 3 years.

People may not be able to take part in this study if they are taking other medicines for their Parkinson's symptoms besides levodopa, have a history of other types of parkinsonian syndromes, are living in a nursing home or assisted care facility or have certain PD symptoms, such as falls or a sudden temporary inability to move. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 6 weeks before the start of treatment.

This is a 'placebo-controlled' study. This means that participants are put in a group that will receive a medicine or in a group that will receive 'placebo' (a medicine that contains no active ingredients but looks the same as the study medicine). Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will join 1 of 2 groups randomly (like flipping a coin) and given either:

- Prasinezumab, given as a drip into the vein (infusion) every 4 weeks

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- OR placebo, given as an infusion every 4 weeks

Participants will have an equal chance of being placed in either group. This is a double-blinded study. This means that neither the participants in the study nor the team running it will know which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

Once participants have completed the double-blinded part of the study they may choose to continue to receive treatment in an extension of the trial. Everyone who joins the extension will be given prasinezumab as an infusion every 4 weeks. The extension is open-label which means everyone involved, including the participant and the study doctor, will know the participant has been given prasinezumab.

During this study, the study doctor will see participants every 4 weeks. They will check for any unwanted effects participants may have and see how well the treatment is working. Participants will have follow-up visits after 10 weeks of completing the study treatment, during which the study doctor will check on the participant's well being. Total time of participation in the study will likely be between 2 and about 3.5 years depending on when they join. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are:

- The time between the start of the study and motor symptoms getting worse

Other key results measured in the study include:

- How much participants' motor symptoms change after 2 years of treatment compared with the start of the study
- The time between the start of the study and participant's reporting that daily functioning symptoms were getting worse once their motor symptoms got worse
- The number, type and seriousness of unwanted effects (safety and tolerability)
- How prasinezumab gets to different parts of the body, and how the body changes and gets rid of it
- The effect of prasinezumab on the the body's natural defence (immune system)

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

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It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicine Participants may have unwanted effects of the medicine used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of prasinezumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include reactions after the infusion with symptoms such as fever, a feeling of coldness that makes the body shiver (chills), low blood pressure, rash, pain or discomfort in the head (headache), feeling or being sick and lack of energy.

The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Body weight within 40-110 kilograms (kg) (88-242 pounds [lbs]) and a body mass index within the range 18-34 kg/m²
- Diagnosis of idiopathic PD based on Movement Disorder Society (MDS) criteria
- Has received monotherapy treatment
- An MDS-UPDRS Part IV score of 0 at screening and prior to randomization
- Hoehn and Yahr (H&Y) Stage 1 or 2 off medication at screening and prior to randomization
- Agreement to adhere to the contraception requirements

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the time frame in which contraception is required
- Medical history indicating a parkinsonian syndrome other than idiopathic PD
- Diagnosis of a significant neurologic disease other than PD
- Chronic uncontrolled hypertension