ForPatients
by Roche

Parkinson's Disease (PD)

A study to evaluate the efficacy and safety of intravenous prasinezumab in participants with early Parkinson's disease

A Study to Evaluate the Efficacy and Safety of Intravenous Prasinezumab in Participants With Early Parkinson's Disease

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	9 Countries	NCT04777331 2020-004997-23 BN42358

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is a multicenter, randomized, double-blind, placebo-controlled study that will evaluate the efficacy and safety of intravenous (IV) prasinezumab versus placebo in participants with Early Parkinson's Disease (PD) who are on stable symptomatic PD medication.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04777331 2020-004997-23 BN42358
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=50 Years & <= 85 Years	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 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. Symptoms include poor balance, feeling tired or weak, and a persistent feeling of sadness and loss of interest that can affect daily functioning. 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. These people are also being treated with other medications for PD 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 MAO-B inhibitors OR levodopa for at least 3 months and have been diagnosed with PD within the last 3 years that is not due to certain inherited genes.

People may not be able to take part in this study if they cannot use a smartphone and smartwatch, 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. Participants who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

Participants may have to be a part of this study for up to 5 years. Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 to 3 months 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 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 be split into 2 groups randomly (like flipping a coin) and given either:

- Prasinezumab, given as a drip into the vein every 4 weeks
- OR placebo, given as a drip into the vein 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 continue to receive treatment in an extension of the trial if they agree to it. Everyone who joins the extension will be given prasinezumab as a drip into the vein 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 3 times during Month 1, then every 4 weeks while being given treatment. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have 2 follow-up visits, the first after 1 month of completing the study treatment and another after 2 and a half months, during which the study doctor will check on the participant’s wellbeing. Total time of participation in the study could be up to 5 years including the study extension. 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 amount of time between the start of the study and motor symptoms getting worse
- The number, type and seriousness of unwanted effects (safety and tolerability)

Other key results measured in the study include:

- The amount of time between the start of the study and participant’s reporting on questionnaires or the study doctor reporting that the participants PD symptoms are getting worse
- The amount of time between the start of the study and participants having motor complications due to standard medicines for PD, such as levodopa
- How much participants’ motor symptoms, such as reduced movement speed and muscle stiffness, change after a year and a half of treatment compared with the start of the study
- The number of participants who stop study treatment due to unwanted effects
- How much participants’ vitals and heart rhythm change compared with the start of the study
- How the body processes prasinezumab and how it affects the 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.

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 of the skin after it has been pricked with a needle to give treatment.

Prasinezumab and placebo will be given as a drip into the vein. Known unwanted effects include feeling or being sick, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, reddening of the skin, headache, a rapid or irregular heart rate, frequent watery stools, shortness of breath, cough and throat irritation or swelling.

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