ForPatients
by Roche

Neurodegenerative Disorder Parkinson's Disease (PD)

A study to evaluate whether Prasinezumab can slow or halt disease progression in people with a recent diagnosis of Parkinson’s disease.

A Study to Evaluate the Efficacy of RO7046015 in Participants With Early Parkinson’s Disease (PASADENA)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT03100149 2017-000087-15,2023-504472-24-00 BP39529

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 multicenter, randomized, double-blind, placebo-controlled, Phase 2 study will evaluate the efficacy of intravenous prasinezumab (RO7046015/PRX002) versus placebo over 52 weeks in participants with early Parkinson's Disease (PD) who are untreated or treated with monoamine oxidase B (MAO-B) inhibitors since baseline. The study will consist of three parts: a 52-week, double-blind, placebo-controlled treatment period (Part 1) after which eligible participants will continue into an all-participants-on-treatment blinded dose extension for an additional 52 weeks (Part 2). Participants who complete Part 2 (including the 12-week treatment-free follow up visit assessing long term safety and efficacy of RO7046015) will be offered participation in Part 3 open-label extension (all-participants-on-RO7046015-treatment) for an additional 260 weeks.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT03100149 2017-000087-15,2023-504472-24-00 BP39529
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 40 Years & <= 80 Years	No

1. How does the PASADENA clinical trial work?

This clinical trial is designed to test whether Prasinezumab can slow or halt disease progression in people who have been diagnosed with Parkinson's disease within the past two years and are in the early stage of the disease, not having started symptomatic treatment with levodopa or dopamine agonists yet.

The study is composed of two consecutive parts in which Parkinson's patients will receive monthly intravenous injection of Prasinezumab or placebo for 52 weeks (Part 1) followed by 52 weeks (Part 2) in which Prasinezumab will be offered to all patients who successfully complete Part 1.

2. How do i take part in this clinical trial?

The recruitment phase of this clinical trial is currently closed, no longer accepting new participants. For more information about criteria regarding this study please see the For Expert tab on the ForPatients page of this study or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/study/NCT03100149?term=NCT03100149&rank=1

3. What treatment will be given if i join this clinical trial?

The first 52-week Part 1 of the study is a 'placebo-controlled' clinical trial, in which one of the groups will be given the active drug Prasinezumab while the other group will receive a drug with no active ingredients (also known as a 'placebo').

For Part 1, everyone who joins this clinical trial will be split into 3 groups randomly (like flipping a coin) and given either:

- Prasinezumab, given at a higher dose intravenous infusion (into the vein) every 4 weeks for up to 52 weeks.
- OR Prasinezumab, given at a lower dose intravenous infusion (into the vein) every 4 weeks for up to 52 weeks.
- OR non-active medicine (placebo), given as an intravenous infusion (into the vein) every 4 weeks for up to 52 weeks.

For Part 1 you will have a one in three chance of being placed in any of the three groups.

For Part 2, participants who received the higher or the lower dose of Prasinezumab during Part 1 will continue to receive that same dose for up to an additional 52 weeks. Participants who received placebo for Part 1 will be split into 2 groups randomly (like flipping a coin) and given either:

- Prasinezumab, given at a higher dose intravenous infusion (into the vein) every 4 weeks for up to 52 weeks.
- OR Prasinezumab, given at a lower dose intravenous infusion (into the vein) every 4 weeks for up to 52 weeks.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

4. How often will i be seen in follow-up appointments, and for how long?

In Part 1 you will be given the clinical trial treatment Prasinezumab OR placebo every 4 weeks for 52 weeks, followed by Prasinezumab every 4 weeks for an additional 52 weeks. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor every 4 weeks when you receive treatment. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

5. What happens if i am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the For Expert tab on the specific ForPatients page or follow this link to ClinicalTrials.gov
https://clinicaltrials.gov/ct2/show/study/NCT03100149?term=NCT03100149&rank=1
Trial-identifier: NCT03100149