ForPatients
by Roche

Neurodegenerative DisorderParkinson'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 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 Randomized, Double-Blind, Placebo-Controlled, 52-Week Phase II Study to Evaluate the Efficacy of Intravenous RO7046015/Prasinezumab (PRX002) in Participants With Early Parkinson's Disease With a 11-Year All-Participants-on-Treatment Extension

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 520 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

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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

Inclusion Criteria:

- Idiopathic PD with bradykinesia plus one of the other cardinal signs of PD (resting tremor, rigidity) being present, without any other known or suspected cause of PD untreated or treated with MAO-B inhibitor
- Body weight range between: >/=45 kg/ 99 pounds (lbs) and less than or equal to (</=) 110 kg/242 lbs
- Body mass index (BMI) of 18 to 34 kilograms per meter-squared (kg/m^2)
- A diagnosis of PD for 2 years or less at screening
- Hoehn and Yahr Stage I or II
- A screening brain DaT-SPECT consistent with PD (central reading)
- Clinical status does not require dopaminergic PD medication and is not expected to require dopaminergic treatment within 52 weeks from baseline
- If presently being treated for PD, a stable dose of MAO-B inhibitor (rasagiline or selegiline) for at least 90 days prior to baseline and not expected to change within 52 weeks
- For women of childbearing potential: use of highly effective contraceptive methods (that result in a failure rate of <1 percent [%] per year) during the treatment period and for at least 30 days (or longer if required by local regulations) after the last dose of study drug
- For men with female partners of childbearing potential or pregnant female partners, must use a condom during the treatment period and for at least 30 days (or longer if required by local regulations) after the

last dose of study drug to avoid exposing the embryo. Men must refrain from donating sperm during this same period. The female partners should use a contraception method with a failure rate of <1% per year during the treatment period and for at least 30 days (or longer if required by local regulations) after the last dose of study drug. Use of contraceptive measures is not required for male participants enrolled in Part 3.

Exclusion Criteria:

- Medical history indicating a Parkinson syndrome other than idiopathic PD, including but not limited to, progressive supranuclear gaze palsy, multiple system atrophy, drug-induced parkinsonism, essential tremor, primary dystonia
- Known carriers of certain familial PD genes (as specified in study protocol)
- History of PD related freezing episodes or falls
- A diagnosis of a significant CNS disease other than Parkinson's disease; history of repeated head injury; history of epilepsy or seizure disorder other than febrile seizures as a child
- Mini Mental State Examination (MMSE) </=25
- Reside in a nursing home or assisted care facility
- History of or screening brain magnetic resonance imaging (MRI) scan indicative of clinically significant abnormality
- Concomitant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the participant in this study or interfere with the participant's ability to comply with study procedures or abide by study restrictions, or with the ability to interpret safety data
- Any significant cardiovascular condition
- Any significant laboratory abnormality
- Lactating women
- Prior treatment with dopaminergic medication (for example, levodopa or a dopaminergic agonist) with no clinical treatment response or a clinical treatment response inconsistent with PD (for example, absence of observable response to a sufficiently high-dose of levodopa [i.e., # 600 mg/day])
- Use of any of the following: catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone), amantadine or anticholinergics, or dopaminergic medication (levodopa and both ergot and non-ergot [pramipexole, ropinirole, rotigotine] dopamine agonists) for more than a total of 60 days or within 60 days of baseline
- Anti-epileptic medication for non-seizure-related treatment which has not remained stable for at least 60 days prior to baseline
- Anti-depressant or anxiolytic use that has not remained stable for at least 90 days prior to baseline. The use of fluoxetine and fluvoxamine is not permitted. For patients treated with a MAO-B inhibitor and an antidepressant (except fluoxetine and fluvoxamine), a 6-month period of stable and tolerated dosing before baseline is required.
- Use of any of the following within 90 days prior to baseline: antipsychotics (including clozapine and olanzapine), metoclopramide, alpha methyldopa, clozapine, olanzapine, flunarizine, amoxapine, amphetamine derivatives, reserpine, bupropion, buspirone, cocaine, mazindol, methamphetamine, methylphenidate, norephedrine, phentermine, phenylpropanolamine, and modafinil
- Participated in an investigational drug, device, surgical , or stem cell study in PD
- Any prior treatment with an investigational PD-related vaccine (including active immunization or passive immunotherapy with monoclonal antibodies).
- Prior participation in any RO7046015 or PRX002 study
- Receipt of any non-PD investigational product or device, or participation in a non-PD drug research study within a period of 30 days (or 5 half-lives of the drug, whichever is longer) before baseline
- Receipt of any monoclonal antibody or an investigational immunomodulator within 180 days (or 5 half-lives, whichever is longer) before baseline
- Immunomodulating drugs within 30 days prior to baseline

- Allergy to any of the components of RO7046015 such as citrate, trehalose and polysorbate (Tween) 20 or a known hypersensitivity or an Infusion-related reaction (IRR) to the administration of any other monoclonal antibody
- Any contraindications to obtaining a brain MRI. Patients with a hypersensitivity to iodine may receive an alternative thyroid blocking agent.
- For participants consenting to provide optional cerebrospinal fluid (CSF) samples by lumbar puncture (LP): LP will only be performed if the participant does not have any contraindication to undergoing an LP
- Donation of blood over 500 milliliters (mL) within three months prior to screening