ForPatients
by Roche

Parkinson's Disease (PD)

A phase 1b, adaptive, multi-center, randomized, double-blind, placebo-controlled, parallel design study to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7486967 in participants with early idiopathic Parkinson's disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	BP43176

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

Trial Summary:

A study to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of RO7486967 in participants with early idiopathic Parkinson's disease

F. Hoffmann-La Roche Ltd (Switzerland), Genentech Inc (USA) Sponsor	**Phase 1b** Phase

BP43176
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	50-85 years	No

Background and study aims:

Parkinson’s disease (PD) is a progressive and incurable disease that affects the nervous system. It is caused by the loss of brain cells that produce dopamine, a chemical that helps brain cells communicate and control movement. The main symptoms include decreased mobility, rigidity or stiffness of arms, legs, and trunk, and resting tremors (shaking that occurs at rest). Evidence suggests that people with PD may have increased inflammation (swelling) in the brain. A protein called NLRP3 is thought to play a key role in this inflammatory process. RO748967 is a new drug that has been developed to slow the progression of disease in people with early PD. RO748967 acts by blocking NLRP3, which might lower the inflammation in the brain. Health authorities have not yet approved RO748967 for the treatment of PD or any other disease. The main purpose of this study is:

-To determine how safe and tolerable RO748967 is when compared to a placebo (medicine without an active ingredient)

-To determine how RO748967 is absorbed, distributed and, eventually eliminated from the body

-To assess the effect of RO748967 on the inflammation in the brain using certain scans called the TSO-PET scans

Who can participate?

People aged between 50 to 85 years with PD.

What does the study involve?

Participants may be asked to be in the study for approximately 100 days. This includes: -

Screening Period of up to 60 days where tests will be done to check if the participants are eligible to take part in the study. Participants may have to visit the clinic approximately 3 times during the Screening Period.

The baseline period of up to 3 days before the start of the study wherein participants will be contacted over the phone to collect details about other medicines and changes to their health and life. MRI and TSPO PET scans will also be done at this time.

Treatment Period of approximately 28 days where participants will have to report 5 times to the clinic and 2 times to a dedicated external PET center for tests, assessments, and procedures in addition to taking the study medication twice a day.

Follow-up Period where participants will have a check-up 14 days after the last study treatment administration.

Participants will be placed in one of the following treatment groups:

Group 1 will receive RO7486967, given as two pills in the morning and two pills in the evening every day for about 4 weeks.

Group 2 will receive a placebo, given as two pills in the morning and two pills in the evening every day for about 4 weeks

What are the possible benefits and risks of participating?

Participants will not receive any benefit from participating in this study, but the information that is learned may help people with PD in the future.

Participants may have side effects from the drugs or procedures used in this study that are mild to severe and even life-threatening in nature, and they can vary from person to person.