

Parkinson's Disease (PD)

Study to Test Effects and Safety of RO7568282 in Early Parkinson's Disease

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07781644 2025-524064-37-00 2025 BP46441

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 II, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of RO7568282 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 RO7568282 compared with placebo in participants with early-stage Parkinson's disease (PD) on stable symptomatic monotherapy with levodopa.

Hoffmann-La Roche Sponsor	Phase 1/Phase 2 Phase
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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#40 Years & # 85 Years	No

Inclusion Criteria:

- Must be aged 40 to 85 years inclusive
- Diagnosis of idiopathic PD
- Has received stable doses of monotherapy treatment with levodopa for at least 2 months prior to baseline
- Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part IV score of 0 at screening and prior to randomization at baseline

ForPatients

by Roche

- Hoehn and Yahr (H&Y) Stage # 3 (assessed in off medication state) at screening and prior to randomization at baseline
- Able to swallow whole capsules

Exclusion Criteria:

- Medical history indicating a parkinsonian syndrome other than idiopathic PD
- Diagnosis of PD dementia
- Diagnosis of a significant neurologic disease other than PD
- Within the last year, unstable or clinically significant cardiovascular disease
- Chronic uncontrolled hypertension
- History or presence of brain magnetic resonance imaging (MRI) scan showing evidence of structural abnormalities, other than related to PD

Note: Other protocol-defined inclusion/exclusion criteria also apply