ForPatients
by Roche

Huntington-Krankheit

Eine Studie zur Beurteilung der Wirksamkeit und Sicherheit von intrathekal verabreichtem RO7234292 (RG6042) bei Patient*innen mit manifester Chorea Huntington

A Study to Evaluate the Efficacy and Safety of Intrathecally Administered RO7234292 (RG6042) in Participants With Manifest Huntington's Disease

Trial Status	Trial Runs In	Trial Identifier
Abgeschlossen	17 Countries	NCT03761849 2018-002987-14 BN40423

Die nachstehenden Informationen zu Klinischen Studien stammen von öffentlichen Registern wie ClinicalTrials.gov, EuClinicalTrials.eu und ISRCTN.com. Weitere patientenfreundliche (laienverständliche) Inhalte wurden von Roche erstellt, um das Verständnis zu erleichtern.

Official Title:

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy and Safety of Intrathecally Administered RO7234292 (RG6042) in Patients With Manifest Huntington's Disease

Trial Summary:

This study will evaluate the efficacy, safety, and biomarker effects of RO7234292 (RG6042) compared with placebo in participants with manifest Huntington's disease (HD)

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03761849 2018-002987-14 BN40423
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#25 Years & # 65 Years	No

Inclusion Criteria:

- Manifest HD diagnosis, defined as a DCL score of 4
- Independence Scale (IS) score >= 70

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- Genetically confirmed disease by direct DNA testing with a CAP score >400
- Clinical assessment to ensure individual has intact functional independence at baseline to maintain self-care and core activities of daily living (ADLs).

Exclusion Criteria:

- Any serious medical condition or clinically significant laboratory, or vital sign abnormality or claustrophobia at screening that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 5 months after the final dose of study drug

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