ForPatients
by Roche

Multiple Sclerosis (MS)Relapsing Multiple Sclerosis (RMS)

Prospective Study to Assess Disease Activity and Biomarkers in Minority Participants With Relapsing Multiple Sclerosis (RMS) After Initiation and During Treatment With Ocrelizumab

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	2 Countries	NCT04377555 ML42071

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:

An Open-Label, Prospective, Single-arm, Multi-center Study to Assess Disease Activity and Biomarkers of Neuronal Damage in Minority Patients With Relapsing Multiple Sclerosis Receiving Treatment With Ocrelizumab

Trial Summary:

Open-label, prospective, single-arm, multi-center study to assess disease activity and biomarker of neuronal damage in minority patients (self-identified Black or African American (AA) and Hispanic/Latino (HA) patients with relapsing multiple sclerosis (RMS) receiving treatment with Ocrelizumab. The study plans to enroll approximately 150 participants (75 AA and 75 HA) with 50 participants enrolled in a CSF sub-study.

Genentech, Inc.
Sponsor

Phase 4
Phase

NCT04377555 ML42071
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 65 Years	No

Inclusion Criteria:

- Diagnosis of RMS with Expanded Disability Status Scale (EDSS) 0-5.5 at enrollment
- Participants who self-identify as Black or African American or Hispanic/Latino American

- Treatment-naïve or initiating first or second switch from receiving treatment with certain disease modifying therapies (DMTs) including interferon or glatiramer acetate or dimethyl fumarate (DMF); or siponimod; or fingolimod; or diroximel fumarate; or teriflunomide; or ozanimod; or natalizumab
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraceptive methods during the treatment period and for 6 months after the final dose of ocrelizumab
- Neurologically stable for at least 30 days prior to randomization and baseline assessments

Exclusion Criteria:

- Diagnosis of secondary progressive MS without relapses for at least 1 year (nonactive or inactive SPMS)
- Primary Progressive Multiple Sclerosis (PPMS)
- Participants with contraindication to gadolinium based contrast agent for MRI and participants who cannot tolerate MRI procedure
- Infection Related
- Cancer Related
- Pregnant or lactating, or intending to become pregnant during the study
- Other Medical Conditions
- Known presence or history of other neurologic disorders
- Vaccinations: Receipt of a live vaccine, or attenuated, or inactivated / component vaccine within 6 weeks prior to first administration of ocrelizumab
- Laboratory: abnormalities or findings at screening