

Multiple Sclerosis (MS)

A Study To Investigate The Pharmacokinetics, Safety, And Tolerability Of Subcutaneous Ocrelizumab Administration In Patients With Multiple Sclerosis

Trial Status
Active, not recruiting

Trial Runs In
1 Country

Trial Identifier
NCT03972306 CN41144

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 Ib, Open-Label, Multicenter Study To Investigate The Pharmacokinetics, Safety, And Tolerability Of Subcutaneous Ocrelizumab Administration In Patients With Multiple Sclerosis

Trial Summary:

This study will evaluate the pharmacokinetics, safety and tolerability, and immunogenicity of ocrelizumab administered subcutaneously to participants with multiple sclerosis (MS).

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT03972306 CN41144
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years & # 65 Years

Healthy Volunteers
No

Inclusion Criteria:

- Diagnosis of Primary Progressive Multiple Sclerosis (PPMS) or Relapsing Multiple Sclerosis (RMS) according to the revised McDonald 2017 criteria (Thompson et al. 2018)
- Expanded Disability Status Scale (EDSS) score, 0-6.5, inclusive, at screening
- Absence of relapses for 30 days prior to the screening visit
- For the dose escalation phase for participants pretreated with ocrelizumab (Group A):

treatment with IV ocrelizumab for at least 1 year prior to screening (i.e., at least two 600-mg doses of ocrelizumab separated by 24 weeks)

- For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods during the treatment period and for 6 months after the final dose of ocrelizumab.
- For female participants without reproductive potential:

Women may be enrolled if post-menopausal unless the participant is receiving a hormonal therapy for her menopause or if surgically sterile (i.e., hysterectomy, complete bilateral oophorectomy).

Exclusion Criteria:

- MS disease duration of more than 15 years for participants with an Expanded Disability Status Scale (EDSS) score <2.0 at screening.
- Known presence of other neurologic disorders that may mimic MS, including, but not limited to, the following:
- History of ischemic cerebrovascular disorders (e.g., stroke, transient ischemic attack) or ischemia of the spinal cord
- History or known presence of Central Nervous System (CNS) or spinal cord tumor (e.g., meningioma, glioma)
- History or known presence of potential metabolic causes of myelopathy (e.g., untreated vitamin B12 deficiency)
- History or known presence of infectious causes of myelopathy (e.g., syphilis, Lyme disease, human T-lymphotropic virus 1, herpes zoster and myelopathy).
- History of genetically inherited progressive CNS degenerative disorder (e.g., hereditary paraparesis and mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke syndrome)
- Neuromyelitis optica
- History or known presence of systemic autoimmune disorders potentially causing progressive neurologic disease (e.g., lupus, anti-phospholipid antibody syndrome, Sjögren syndrome, Behçet disease, sarcoidosis).
- History of severe, clinically significant brain or spinal cord trauma (e.g., cerebral contusion, spinal cord compression)