ForPatients
by Roche

Multiple Sclerosis (MS)Relapsing-Remitting Multiple Sclerosis (RRMS)

A Study to Evaluate Pharmacokinetics, Safety, Tolerability, Immunogenicity and Pharmacodynamic Effects of Subcutaneous Ocrelizumab Administration in Children and Adolescents With Relapsing-remitting Multiple Sclerosis (RRMS)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07503340 2025-524164-37-00 BA45841

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 Study to Evaluate Pharmacokinetics, Safety, Tolerability, Immunogenicity and Pharmacodynamic Effects of Subcutaneous Ocrelizumab Administration in Children and Adolescents With Relapsing-remitting Multiple Sclerosis

Trial Summary:

The main purpose of this study is to evaluate the pharmacokinetics (PK) of ocrelizumab administered subcutaneously (SC) in children and adolescents aged 10 to <18 years with RRMS. The study consists of a 48-week treatment period, an Optional Ocrelizumab Extension (OOE) period of at least 48 weeks, and Safety Follow-up (SFU) for 104 weeks.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT07503340 2025-524164-37-00 BA45841
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#10 Years & # 17 Years	No

Inclusion Criteria:

- Children and adolescents from 10 years to less than 18 years of age, at the time of baseline visit

- Body weight #25 kg
- Diagnosis of RRMS in accordance with the International Pediatric Multiple Sclerosis Study Group (IPMSSG) criteria for pediatric MS, Version 2012, or McDonald criteria 2017 or 2024
- Neurologic stability for at least 30 days prior to screening, and between screening and baseline
- Expanded Disability Status Scale (EDSS) score, 0-5.5, at screening
- Must have received all childhood required vaccinations as per local/national recommendations for childhood vaccination against infectious diseases

Exclusion Criteria:

- Participants who are positive for aquaporin 4 (AQP4) or myelin oligodendrocyte glycoprotein (MOG) antibody are not eligible to participate in the study
- Any known presence or suspicion of other neurologic disorders that may mimic multiple sclerosis (MS)
- History or known presence of recurrent or chronic infection (e.g., human immunodeficiency virus [HIV], syphilis, tuberculosis [TB])
- Contraindications against SC injections or other conditions not suitable for SC injections, e.g., extremely thin SC fat layer
- History of a severe allergic or anaphylactic reaction to humanized or murine monoclonal antibody or known hypersensitivity to any component of ocrelizumab solution
- Contraindications to mandatory premedications (i.e., corticosteroids and histamines), including closed-angle glaucoma for antihistamines
- Participants who have previously received treatment with B cell-targeted therapies, including ocrelizumab
- Any previous treatment with alemtuzumab, anti-CD4, cladribine, mitoxantrone, daclizumab, laquinimod, total body irradiation, or bone marrow transplantation
- Treatment with any investigational agent within 24 weeks of screening or 5 half-lives, whichever is longer (or longer if indicated by the PD action of the drug)