ForPatients
by Roche

Multiple Sclerosis (MS)

A Study of Ocrelizumab in Comparison With Interferon Beta-1a (Rebif) in Participants With Relapsing Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Completed	32 Countries	NCT01247324 2010-020337-99 WA21092

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 Randomized, Double-Blind, Double-Dummy, Parallel-Group Study To Evaluate the Efficacy and Safety of Ocrelizumab in Comparison to Interferon Beta-1a (Rebif®) in Patients With Relapsing Multiple Sclerosis

Trial Summary:

This randomized, double-blind, double-dummy, parallel-group study will evaluate the efficacy and safety of ocrelizumab in comparison with interferon beta-1a (Rebif) in participants with relapsing multiple sclerosis. Participants will be randomized to receive either ocrelizumab 600 mg or matching placebo intravenous (IV) as 300 mg infusions on Days 1 and 15 for the first dose and as a single infusion of 600 mg for all subsequent infusions every 24 weeks, with placebo injections matching interferon beta-1a SC three times per week; or interferon beta-1a 44 mcg SC injections three times per week (with placebo infusions matching ocrelizumab infusions every 24 weeks). Planned duration of double-blind treatment is 96 weeks. Participants who complete the 96-week double-blind treatment will have an option to enter a single-group, active-treatment, open-label extension period, providing they fulfill the eligibility criteria.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT01247324 2010-020337-99 WA21092
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 55 Years	No

Inclusion Criteria:

- Diagnosis of multiple sclerosis, in accordance with the revised McDonald criteria (2010)
- At least 2 documented clinical attacks within the last 2 years prior to screening or one clinical attack in the years prior to screening (but not within 30 days prior to screening)
- Neurologic stability for greater than or equal to (>=) 30 days prior to both screening and baseline
- Expanded Disability Status Scale (EDSS) score 0 to 5.5 inclusive

Exclusion Criteria:

- Primary progressive multiple sclerosis
- Disease duration of more than 10 years in participants with EDSS less than or equal to (<=) 2.0 at screening
- Contraindications for MRI
- Known presence of other neurological disorders which may mimic multiple sclerosis
- Pregnancy or lactation
- Requirement for chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- History of or currently active primary or secondary immunodeficiency
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- Active infection, or history of or known presence of recurrent or chronic infection (e.g., hepatitis B or C, human immunodeficiency virus [HIV], syphilis, tuberculosis)
- History of progressive multifocal leukoencephalopathy
- Contraindications to or intolerance of oral or iv corticosteroids
- Contraindications to Rebif or incompatibility with Rebif use