

Multiple Sclerosis (MS)

A Study to Evaluate the Effects of Ocrelizumab on Immune Responses In Participants With Relapsing Forms of Multiple Sclerosis

Trial Status
Completed

Trial Runs In
2 Countries

Trial Identifier
NCT02545868 2015-001357-32
BN29739

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 IIIB, Multicenter, Randomized, Parallel-Group, Open-Label Study to Evaluate the Effects of Ocrelizumab on Immune Responses in Patients With Relapsing Forms of Multiple Sclerosis

Trial Summary:

This multicenter, randomized, open-label study will evaluate the immune response to vaccines (tetanus toxoid [TT]-containing adsorbed vaccine, 23-valent pneumococcal polysaccharide vaccine [23-PPV] either unboosted or boosted with 13-valent pneumococcal conjugate vaccine [13-PCV], influenza vaccine, keyhole limpet hemocyanin [KLH]) after administration of a dose of ocrelizumab (OCR) in participants with relapsing multiple sclerosis (RMS).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Eligibility Criteria:

Gender
All

Age
#18 Years & # 55 Years

Healthy Volunteers
No

Inclusion Criteria:

- Diagnosis of RMS in accordance with the revised McDonald criteria
- Received at least one previous immunization against TT or tetanus and diphtheria (DT/Td) or tetanus, diphtheria, and acellular pertussis (DTaP/Tdap)

ForPatients

by Roche

- Expanded Disability Status Scale (EDSS) at Screening from 0 to 5.5 points, inclusive
- For sexually active female participants of reproductive potential, use of reliable means of contraception

Exclusion Criteria:

- Contraindications for or intolerance to oral or IV corticosteroids, including IV methylprednisolone, according to the country label
- Known presence of other neurologic disorders
- Treatment with any investigational agent within 24 weeks of screening or 5 half-lives of the investigational drug, whichever is longer, or treatment with any experimental procedure for multiple sclerosis