ForPatients
by Roche

Multiple Sclerosis (MS)

A Study to Evaluate the Safety of Administering Ocrelizumab Per a Shorter Infusion Protocol in Participants With Primary Progressive Multiple Sclerosis (PPMS) and Relapsing Multiple Sclerosis (RMS).

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT03606460 ML40638

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study is an open-label, non-randomized study to evaluate rate and severity of infusion-related reactions (IRRs) of ocrelizumab infused over a shorter time period than the approved administration rate in participants with PPMS or RMS in the United States (U.S.). Participants will be enrolled into two cohorts. Cohort 1 will examine the effect of administering ocrelizumab per a shorter infusion protocol for Dose 2 or Dose 3. This cohort will consist of patients who have already received one or two doses of ocrelizumab according to the approved infusion protocol (i.e., per the currently U.S. label) and have reported no serious IRRs and who will then receive the next infusion of ocrelizumab at a higher rate in order to deliver 600 mg over the course of approximately 2 hours. Cohort 2 will examine the effect of administering ocrelizumab per a shorter infusion protocol for the second infusion of Dose 1. This cohort will consist of ocrelizumab naïve patients who, after receiving Infusion 1/Dose 1 of ocrelizumab at the approved rate (300 mg over approximately 2.5 hours or longer) have no reported serious IRRs, will then receive the second 300-mg shorter infusion over approximately 1.5 hours.

Genentech, Inc.	Phase 3
Sponsor	Phase

NCT03606460 ML40638
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 55 Years	No

© 2022 F. Hoffmann-La Roche Ltd