ForPatients
by Roche

Autoimmune Disorder

A Study Evaluating the Safety and Efficacy of Rituximab in Combination With Glucocorticoids in Participants With Wegener's Granulomatosis or Microscopic Polyangitis

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02115997 ML28550

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 is a perspective, Phase IV, multi-center, single arm, open-label, interventional study in adult participants with Wegener's granulomatosis (granulomatosis with polyangiitis [GPA]) or microscopic polyangiitis. Participants will be treated with rituximab (Ristova) and glucocorticoids. Rituximab will be administered by intravenous (IV) infusion at a dose of 375 milligrams per meter square (mg/m^2) body surface area once weekly during Weeks 1 to 4. Participants will also receive one or three pulses of methylprednisolone (1000 milligram [mg] each), followed by a tapering dose of oral prednisolone (start dose of 1 mg per kilogram per day). The dose of oral prednisone will be reduced as per evaluation by the investigator till the participant is completely off the drug. The participants will be followed up for duration of 6 months from the date of starting rituximab therapy with three follow-up visits at Days 52, 112 and 172. All adverse events occurring during this period will be captured.

Hoffmann-La Roche Sponsor	**Phase 4** Phase
NCT02115997 ML28550 Trial Identifiers	

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No