

Autoimmune Disorder

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

Trial Status

Active, not recruiting

Trial Runs In

1 Countries

Trial Identifier

NCT02115997 ML28550

The source of the below information is the publicly available website [ClinicalTrials.gov](https://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/m²) 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

All

Age

>=18 Years

Healthy Volunteers

No