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 Country	NCT02115997 ML28550

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:

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

Inclusion Criteria:

- Male or non-pregnant, non-nursing female
- Diagnosed with Wegener's granulomatosis or Microscopic polyangiitis according to the definitions of the Chapel Hill Consensus Conference
- Participants with either newly diagnosed or relapsing disease
- Participants must have active disease as per the BVAS/WG greater than equal to (>/=) 3 that would normally require treatment with cyclophosphamide (CYC)
- Participants willing to practice medically acceptable contraception during and 1 year after the completion of rituximab therapy
- Participants must have severe disease i.e. one or more of the major BVAS/WG items depicting severity or disease severe enough to require treatment with CYC.
- Participants must be positive for either proteinase 3-antineutrophil cytoplasmic antibodies (PR3-ANCA) or myeloperoxidase-antineutrophil cytoplasmic antibodies (MPO-ANCA) at the screening

Exclusion Criteria:

- History of severe allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies
- Participants in a severely immunocompromised state
- Participants with severe heart failure (New York Heart Association Class IV) or severe, uncontrolled cardiac disease
- Participants having active severe infection or history of recurrent bacterial, viral, fungal, mycobacterial or other infections
- Participants who had a live vaccine fewer than 4 weeks before first dose of rituximab
- Any other condition which puts the participant to undue risk for rituximab therapy as per local prescribing information or Investigator's judgment
- Participants with any previous treatment with rituximab
- Participants with any previous treatment with alemtuzumab
- Participants who have had treatment with infliximab within the previous 3 months
- Participants who have had treatment with adalimumab within the previous 2 months
- Participants who have had treatment with etanercept within the previous month
- Participants with any other investigational medication within the previous month