ForPatients
by Roche

Autoimmune Disorder

A Study to Evaluate the Efficacy and Safety of Rituximab Versus Mycophenolate Mofetil (MMF) in Participants With Pemphigus Vulgaris (PV)

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT02383589 2014-000382-41 WA29330

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 Phase III, randomized, double-blind, double-dummy, active-comparator, parallel-arm, multicenter study to evaluate the efficacy and safety of rituximab compared with MMF in participants with moderate-to-severely active PV requiring 60-120 milligrams per day (mg/day) oral prednisone or equivalent. Participants must have a confirmed diagnosis of PV within the previous 24 months (by skin or mucosal biopsy and immunohistochemistry) and evidence of active disease at screening. Approximately 135 participants will be enrolled at up to 60 centers worldwide. Participants will be randomized in a 1:1 ratio to receive either rituximab plus MMF placebo or rituximab placebo plus MMF. Randomization will be stratified by duration of illness. The study will consist of three periods: a screening period of up to 28 days, a 52-week double-blind treatment period, and a 48-week safety follow up period that begins at the time of study treatment completion or discontinuation.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 75 Years	No