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 information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized, Double-Blind, Double-Dummy, Active-Comparator, Multicenter Study to Evaluate the Efficacy and Safety of Rituximab Versus MMF in Patients With Pemphigus Vulgaris

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
Sponsor

Phase 3
Phase

NCT02383589 2014-000382-41 WA29330
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

All	#18 Years & # 75 Years	No

Inclusion Criteria:

- Confirmed diagnosis of PV within the previous 24 months, based on the presence of histological features of acantholysis via skin or mucosal biopsy and one of the following: tissue bound immunoglobulin G (IgG) antibodies by direct immunofluorescence on the surface of affected epithelium or serological detection of serum desmoglein-3 (DSg3) autoantibodies against epithelial cell surface either by indirect immunofluorescence microscopy or by enzyme-linked immunosorbent assay
- Presence of moderate-to-severely active disease, defined as overall PDAI activity score of greater than or equal to (>/=)15
- Receiving standard-of-care corticosteroids consisting of 60-120 mg/day oral prednisone or equivalent and, in the judgment of the investigator, expected to benefit from the addition of immunosuppressive therapy
- For women who are not postmenopausal (>/=12 months of non-therapy-induced amenorrhea) or surgically sterile (absence of ovaries and/or uterus): agreement to remain abstinent or use two effective methods of contraception, including at least one method with a failure rate of less than (<) 1 percent (%) per year, during the treatment period and for at least 12 months after the last dose of study treatment

Abstinence is acceptable only if it is in line with the preferred and usual lifestyle of the participant. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception

Barrier methods must always be supplemented with the use of a spermicide

Examples of contraceptive methods with a failure rate of < 1% per year (highly effective contraceptive methods) include tubal ligation, male sterilization, hormonal implants, established, proper use of combined oral or injected hormonal contraceptives, and certain intrauterine devices

- For men (including those who have undergone a vasectomy): agreement to remain abstinent or use a condom during the treatment period and for at least 12 months after the last dose of study treatment and agreement to refrain from donating sperm during this same period

Abstinence is only acceptable if it is in line with the preferred and usual lifestyle of the participant

Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. In addition to male contraception, agreement to advise female partners of childbearing potential to use highly effective contraception during the study and for at least 12 months after the last dose of study treatment

- Agreement to avoid excessive exposure to sunlight during study participation
- Able to comply with the study protocol, in the investigator's judgment

Exclusion Criteria:

- Diagnosis of pemphigus foliaceus or evidence of paraneoplastic pemphigus or other non-PV autoimmune blistering disease
- History of a severe allergic or anaphylactic reaction to humanized or murine monoclonal antibodies, or known hypersensitivity to any component of rituximab
- Known hypersensitivity or contraindication to MMF, mycophenolic acid, polysorbate, or oral corticosteroids
- Lack of peripheral venous access
- Pregnant or lactating, or intending to become pregnant during the study

Women who are not postmenopausal (>/=12 months of non-therapy-induced amenorrhea) or surgically sterile must have two negative results with a sensitivity of >/=25 milli-international units per milliliter (mIU/mL): one from a serum pregnancy test at Day -8 to Day -10 of screening and another from a urine pregnancy test at Day 1 prior to randomization

- Participated in another interventional clinical trial within 28 days prior to randomization
- Use of any investigational agent within 28 days or 5 elimination half-lives prior to randomization (whichever is the longer)
- Significant cardiovascular or pulmonary disease (including obstructive pulmonary disease)
- Evidence of any new or uncontrolled concomitant disease that, in the investigator's judgment, would preclude participant participation, including but not limited to nervous system, renal, hepatic, endocrine, malignant, or gastrointestinal disorders
- Any concomitant condition that required treatment with oral or systemic corticosteroids within 12 weeks prior to randomization
- Treatment with intravenous (IV) immunoglobulin (Ig), plasmapheresis, or other similar procedure within 8 weeks prior to randomization
- Treatment with immunosuppressive medications (e.g., azathioprine, MMF) within 1 week prior to randomization
- Treatment with cyclophosphamide within 12 weeks prior to randomization
- History of or currently active primary or secondary immunodeficiency, including known history of HIV infection and other severe immunodeficiency blood disorders
- Known active infection of any kind (excluding fungal infections of nail beds) or any major episode of infection requiring hospitalization or treatment with IV anti-infectives within 4 weeks prior to screening, or completion of oral anti-infectives within 2 weeks prior to randomization; entry into this study may be reconsidered once the infection has fully resolved
- History of or current cancer, including solid tumors, hematologic malignancies, and carcinoma in situ (except complete excision of basal cell of the skin and squamous cell carcinoma of the skin that have been treated or excised and cured)
- Currently active alcohol or drug abuse, or history of alcohol or drug abuse within 24 weeks prior to screening
- Major surgery within 4 weeks prior to randomization, excluding diagnostic surgery
- Treatment with rituximab or a B cell-targeted therapy (e.g., anti-cluster of differentiation [CD] 20 [CD20], anti CD22, or anti-B-lymphocyte stimulator [BLyS]) within 12 months prior to randomization
- Treatment with a live or attenuated vaccine within 28 days prior to randomization; it is recommended that a participant's vaccination record and the need for immunization prior to study entry be carefully investigated
- Evidence of abnormal liver enzymes or hematology laboratory values
- Positive test results for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (HBcAb), or hepatitis C virus (HCV) serology at screening