ForPatients
by Roche

Rheumatoid Arthritis

Study to Compare the Efficacy of Tocilizumab With or Without Glucocorticoid Discontinuation in Rheumatoid Arthritis Participants

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT02573012 2014-004673-16 MA29585

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:

Prospective, Multicentre, Placebo-controlled, Double-blind Interventional Study to Compare the Efficacy of Maintenance Treatment With Tocilizumab With or Without Glucocorticoid Discontinuation in Rheumatoid Arthritis Patients

Trial Summary:

This Phase IIIb/IV, two-arm, randomized, double-blind, placebo-controlled, parallel-group, international, multicenter trial compares the change in disease activity (as assessed by Disease Activity Score in 28 joints [DAS28] erythrocyte sedimentation rate [ESR]) from randomization to Week 24 post-randomization, in participants with stable low disease activity [LDA] (DAS28 ESR score less than or equal to [<=] 3.2) who receive tocilizumab, and have been randomized to either continue or taper prednisone in a double-blinded fashion.

Hoffmann-La Roche
Sponsor

Phase 4
Phase

NCT02573012 2014-004673-16 MA29585
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

Tocilizumab-experienced participants:

- Comply with the requirements of the study protocol (including treatment on an outpatient basis)
- Rheumatoid arthritis (RA) of greater than or equal to (>=) 6 months duration diagnosed according to the revised 1987 American College of Rheumatology (ACR) criteria or 2010 ACR / European League Against Rheumatism (EULAR) criteria
- Have received tocilizumab either subcutaneous (162 milligram [mg] once in a week) or intravenously (8 milligram per kilogram [mg/kg] once every 4 weeks) for the treatment of RA for at least 24 weeks prior to randomization
- Have received 5 - 15 milligrams per day [mg/day] of glucocorticoids (prednisone or equivalent) for the treatment of RA for at least 20 weeks prior to screening
- Currently receiving 5 mg/day of prednisone
- Have attained and maintained LDA (DAS28 ESR score <=3.2) or remission (DAS28 ESR score less than [<] 2.6) for at least 4 weeks prior to randomization

Tocilizumab-naïve participants:

- Comply with the requirements of the study protocol (including treatment on an outpatient basis)
- RA of >=6 months duration diagnosed according to the revised 1987 ACR criteria or 2010 ACR / EULAR criteria
- Have active RA (defined as DAS28 ESR score greater than [>] 3.2)
- Are considered by the investigator as inadequate responders to conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) or biologic disease-modifying anti-rheumatic drugs (bDMARDs)
- Are receiving 5 - 15 mg/day prednisone (or equivalent) for the treatment of RA

Exclusion Criteria:

General

- Major surgery (including joint surgery) within 8 weeks prior to screening, or planned major surgery during the study and up to 6 months after randomization
- Pregnant women or nursing (breastfeeding) mothers
- In females of childbearing potential, a positive serum pregnancy test at screening
- Females of childbearing potential unwilling or unable to use a reliable means of contraception (for example, physical barrier [participant or partner], contraceptive pill or patch, spermicide and barrier, or intrauterine device) during study treatment and for a minimum of 3 months after the last dose of tocilizumab
- Body weight of >=150 kilogram (kg)
- Lack of peripheral venous access

Disease-related

- RA of functional Class 4, as defined by the ACR Classification of Functional Status in Rheumatoid Arthritis
- Rheumatic autoimmune disease other than RA, including systemic lupus erythematosus, mixed connective tissue disease, scleroderma, polymyositis, or significant systemic involvement secondary to RA (for example, vasculitis, pulmonary fibrosis, or Felty syndrome). Secondary Sjögren syndrome with RA may be allowed per the discretion of the investigator
- Diagnosed with juvenile idiopathic arthritis or juvenile RA and/or RA before the age of 16 years
- Prior or current inflammatory joint disease other than RA (for example, gout, Lyme disease, sero-negative spondyloarthropathy, including reactive arthritis, psoriatic arthritis, arthropathy of inflammatory bowel disease), or prior or current joint infections
- Previous history of primary or secondary adrenal insufficiency

Previous or Concomitant Prohibited Therapy

- Treatment with any investigational agent within 4 weeks (or 5 half-lives of the investigational drug, whichever is longer) of screening
- Previous treatment with any cell-depleting therapies, including investigational agents or approved therapies (for example, CAMPATH, anti-CD4, anti-CD5, anti-CD3, anti-CD19, anti-CD20)
- Treatment with intravenous gamma globulin, plasmapheresis or Prosorba column within 6 months of screening
- Intraarticular (IA) or parenteral glucocorticoids for the treatment of RA within 4 weeks prior to screening
- Previous treatment with glucocorticoids for conditions other than RA, at any dose and in any formulation used continuously for >1 week, during the last 1 year prior to screening. Topical glucocorticoid creams or ointments for the treatment of skin conditions (for example eczema) are allowed
- Immunization with a live/attenuated vaccine within 30 days prior to screening. Participants must agree not to take live attenuated vaccines (including seasonal nasal flu vaccine, varicella vaccine for shingles or chickenpox, vaccines for measles, mumps or rubella without or with varicella [MMR or MMRV], oral polio vaccine and vaccines for yellow fever), within 30 days before the Screening Visit, throughout the duration of the trial and for 60 days following the last dose of study drug
- Any previous treatment with alkylating agents such as chlorambucil or with total lymphoid irradiation

Laboratory Exclusion Criteria

- Inadequate haematological, renal and liver function
- Positive hepatitis B surface antigen or hepatitis C antibody Previous or Concomitant Conditions
- History of severe allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies
- Evidence of current serious uncontrolled cardiovascular (including uncontrolled hyperlipidemia), nervous system, pulmonary (including obstructive pulmonary disease), renal, hepatic, endocrine (including uncontrolled diabetes mellitus) or gastrointestinal (GI) disease
- Current liver disease as determined by the investigator
- History of diverticulitis, peptic ulcer disease, diverticulosis requiring antibiotic treatment, or chronic ulcerative lower GI disease such as Crohn's disease, ulcerative colitis, or other symptomatic lower gastrointestinal conditions that might predispose to perforations
- Known active current or history of recurrent bacterial, viral, fungal, mycobacterial, or other opportunistic infections (including, but not limited to, tuberculosis [TB] and atypical mycobacterial disease, hepatitis B and C, Epstein-Barr virus, cytomegalovirus and herpes zoster, but excluding fungal infections of nail beds)
- Neuropathies or other conditions that might interfere with pain evaluation unless related to primary disease under investigation
- Any major episode of infection requiring hospitalization or treatment with intravenous antibiotics within 4 weeks of screening or oral antibiotics within 2 weeks prior to screening
- Active TB requiring treatment within the previous 3 years (participants previously treated for TB with no recurrence within 3 years are permitted). All Track tocilizumab-naïve participants must be screened for latent TB and if positive, should be treated following local practice guidelines prior to initiating tocilizumab
- History of or currently active, primary or secondary immunodeficiency
- Evidence of active malignant disease, malignancies diagnosed within the previous 10 years (including haematological malignancies and solid tumours, except basal and squamous cell carcinoma of the skin or carcinoma in situ of the cervix uteri that was excised and cured), or breast cancer diagnosed within the previous 20 years
- History of alcohol, drug or chemical abuse within 1 year prior to screening
- Pre-existing central nervous system (CNS) demyelination or seizure disorders

- Any medical or psychological condition that in the opinion of the principal investigator would interfere with safe completion of the trial