ForPatients
by Roche

Multiple Sclerosis (MS)

A Study To Determine The Effect Of Ocrelizumab On Leptomeningeal Inflammation In Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	1 Country	NCT05208840 ML42302

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:

Open-Label Multicenter Study To Determine The Effect Of Ocrelizumab On Leptomeningeal Inflammation In Multiple Sclerosis

Trial Summary:

This study will evaluate the evolution of leptomeningeal lesions via leptomeningeal contrast enhancement (LMCE) presence/disappearance after treatment administration in patients with active progressive multiple sclerosis (MS). In addition, this study will investigate if the presence of leptomeningeal inflammation is associated with alterations of B cell repertoire and whether therapy with ocrelizumab will lead to change of B cell repertoire in LMCE-positive patients.

Hoffmann-La Roche
Sponsor

Phase 4
Phase

NCT05208840 ML42302
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 65 Years	No

Inclusion Criteria:

- Patients of both genders with active progressive multiple sclerosis, defined with Lublin 2013 classification: primary progressive multiple sclerosis with subsequent relapses or MRI activity (McDonald 2017 criteria), secondary progressive multiple sclerosis with relapses or MRI activity during 2 years prior to initiation of ocrelizumab.

- It is indicated to treat patients with ocrelizumab according to local regulations.
- EDSS # 6.0.
- Readiness for blood sampling from peripheral vein puncture.
- Neurological stability (no clinically significant worsening according to neurological examination) for #30 days prior to both screening and baseline

Exclusion Criteria:

- Inability to undergo MRI due to devices or metallic foreign bodies considered unsafe in the MRI magnet (contraindications for MRI include but are not restricted to claustrophobia, weight # 140 kg, pacemaker, cochlear implants, presence of foreign substances in the eye, intracranial vascular clips, surgery within 6 weeks of entry into the study, coronary stent implanted within 8 weeks prior to the time of the intended MRI, etc.).
- Known presence of other neurological disorders which may mimic MS including but not limited to: neuromeylitis optica, Lyme disease, untreated vitamin B12 deficiency, neurosarcoidosis and cerebrovascular disorders.
- Known allergies to contrast agent.
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 6 months after the final dose of ocrelizumab.

Women of childbearing potential must have a negative serum pregnancy test result at screening.

- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study.
- History or currently active primary or secondary immunodeficiency.
- Moderately to severe kidney function decreased or severe kidney failure (Glomerular filtration rate <45 mL/min/1.73 m2 as calculated through use of the Chronic Kidney Disease Epidemiology Collaboration equation).
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies.
- Significant or uncontrolled somatic disease or any other significant disease that may preclude patient from participating in the study.
- Congestive heart failure (NYHA III or IV functional severity).
- Known active bacterial, viral, fungal, mycobacterial infection or other infection, excluding fungal infection of nail beds.
- Infection requiring hospitalization or treatment with intravenous antibiotics within 4 weeks prior to the Baseline visit or oral antibiotics within 2 weeks prior to the Baseline visit.
- History or known presence of recurrent or chronic infection (e.g., hepatitis B or C, HIV, syphilis, tuberculosis).
- History of progressive multifocal leukoencephalopathy (PML).
- History of malignancy, including solid tumors and hematological malignancies, except basal cell carcinoma, in situ squamous cell carcinoma of the skin, and in situ carcinoma of the cervix of the uterus that have been previously completely excised with documented, clear margins.
- History of illicit drug or alcohol abuse within 24 weeks prior to screening, in the investigator's judgment.
- History or laboratory evidence of coagulation disorders.
- Receipt of a live vaccine within 6 weeks prior to baseline.
- Treatment with any investigational agent within screening period or five half-lives of the investigational drug (whichever is longer).
- Contraindications to or intolerance of oral or intravenous corticosteroids, including methylprednisolone administered intravenously, according to the country label, including: psychosis not yet controlled by a treatment and hypersensitivity to any of the constituents.

- Previous therapy with B-cell depleting agents (i.e. rituximab, ocrelizumab, atacicept, belimumab or ofatumumab).
- Systemic corticosteroid therapy within 4 weeks prior to screening.
- Any previous treatment with alemtuzumab, anti-CD4 antibodies, cladribine, mitoxantrone, daclizumab, dimethyl fumarate, teriflunomide, laquinimod, total body irradiation or bone marrow transplantation.
- Treatment with cyclophosphamide, azathioprine, mycophenolate mofetil (MMF), cyclosporine, methotrexate or natalizumab within 24 months prior to screening.
- Treatment with fingolimod or other S1P receptor modulator within 24 weeks prior to screening.
- Treatment with intravenous immunoglobulin within 12 weeks prior to baseline.
- Positive screening tests for hepatitis B (hepatitis B surface antigen [HBsAg] positive, or positive hepatitis B core antibody [total HBcAb] confirmed by a positive viral deoxyribonucleic acid [DNA] polymerase chain reaction [PCR]) or hepatitis C (HepCAb).
- Positive syphilis (RPR) test
- Positive HIV infection serological test