Ocrelizumab Discontinuation in Relapsing Multiple Sclerosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 55 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Have at least one clinical episode that satisfies McDonald 2017 criteria for early Multiple sclerosis (MS) for up to 2 years post-event with a dissemination in time that can be met clinically, by Magnetic Resonance Imaging (MRI), or based on oligoclonal band (OCB) positivity 2. Have a length of disease duration, from first symptom, of ≤ 2 years 3. For women of childbearing potential: Agreement to remain abstinent (refrain from heterosexual intercourse) or use effective methods of contraception during the treatment period and for at least 6 months after the last dose of study drug: 1. A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (≥12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus) 2. Examples of contraceptive methods include bilateral tubal ligation, male sterilization, established hormonal contraceptives that inhibit ovulation, hormone- releasing intrauterine devices, and copper intrauterine devices 3. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the participant. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or post ovulation methods) and withdrawal are not acceptable methods of contraception 4. Barrier methods must always be supplemented with the use of a spermicide

---

Exclusion Criteria:

1. Inability or unwillingness of a participant to give written informed consent or comply with study protocol 2. History of Primary Progressive Multiple Sclerosis (PPMS), Progressive Relapsing Multiple Sclerosis (PRMS), or Secondary Progressive Multiple Sclerosis (SPMS) 3. Any metallic material or electronic device in the body, or condition that precludes the participant from undergoing Magnetic resonance imaging (MRI) 4. Known presence or history of other neurological disorders, including but not limited to the following: 1. Ischemic cerebrovascular disorders, including but not limited to transient ischemic attack, subarachnoid hemorrhage, cerebral thrombosis, cerebral embolism, or cerebral hemorrhage 2. Central Nervous System (CNS) or spinal cord tumor, metabolic or infectious cause of myelopathy, genetically inherited progressive CNS disorder, CNS sarcoidosis, or systemic autoimmune disorders potentially causing progressive neurologic disease or affecting ability to perform the study assessments 5. Pregnancy or lactation a. Female participants of childbearing potential must have a negative urine pregnancy test at screening 6. Any concomitant disease that may require chronic systemic treatment with corticosteroids or immunosuppressants during the course of the study 7. Lack of peripheral venous access 8. History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies 9. Significant, inadequately controlled (e.g. diagnostic evaluations indicated or change in medications warranted) disease, such as cardiovascular (including cardiac arrhythmia), pulmonary (including obstructive pulmonary disease), renal, hepatic, endocrine, and gastrointestinal or any other significant disease that in the opinion of the investigator may preclude participant from participating in the study 10. Functional status of NY Heart Association (NYHA) Class III or higher for heart failure at the screening visit 11. Known active bacterial, viral, fungal, mycobacterial infection or other infection (including tuberculosis \[TB\] or atypical mycobacterial disease but excluding limited superficial fungal or viral infections of the skin or nails) or any severe episode of infection requiring hospitalization or treatment with Intravenous (IV) antibiotics within 4 weeks prior to baseline visit or oral antibiotics within 2 weeks prior to baseline visit 12. Active or chronic infection with Human Immunodeficiency Virus (HIV), syphilis or TB (see laboratory tests below) 13. Evidence of past or current hepatitis B or hepatitis C infection, including treated hepatitis B or hepatitis C. Hepatitis B surface antibody following hepatitis B immunization is not considered to be evidence of past infection 14. Known active malignancy or active monitoring for recurrence of malignancy, including solid tumors and hematological malignancies, except basal cell, in situ squamous cell carcinoma of the skin, and in situ carcinoma of the cervix or the uterus that have been excised with clear margins 15. Substance use disorder, including the recurrent use of alcohol and/or drugs within the past year associated with clinically significant impairment associated with failure to meet major responsibilities at work, school, or home 16. Receipt of live or live-attenuated vaccines within 4 weeks prior to baseline 17. Contraindications to or severe intolerance of oral or IV corticosteroids, including Intravenous (IV) methylprednisolone administered according to the country label, including: 1. Psychosis not controlled by a treatment 2. Hypersensitivity to any of the constituents or excipients of the preceding steroids 18. Current or prior treatment with the following MS DMTs: fingolimod and other S1P receptor modulators, cladribine, natalizumab, anti-CD20 molecules, alemtuzumab, and chemotherapeutic agents 19. Treatment with fumarates within 30 days prior to baseline 20. Current or prior treatment with any experimental therapies (e.g., bone marrow transplant), investigational agent, or treatment with any experimental procedure for MS (e.g., treatment for chronic cerebrospinal venous insufficiency) 21. Systemic corticosteroid therapy within 4 weeks prior to screening 22. Laboratory test results as follows: a. Positive infection screening tests for: i. Hepatitis B surface antigen (HbsAg) or hepatitis B core antibody (HbcAb) ii. Hepatitis C (HCV) antibody, if positive screen for HCV RNA Polymerase Chain Reaction (PCR) iii. Rapid plasma reagin (RPR) iv. HIV v. At or within twelve months of screening: * Positive QuantiFERON(R)-TB Gold test or positive purified protein derivative tuberculin skin test (PPD) (\>5mm induration, regardless of Bacille Calmette Guerin \[BCG\] vaccine administration) unless completion of treatment has been documented for active TB * An indeterminate QuantiFERON(R)-TB Gold test unless followed by a subsequent negative PPD or negative QuantiFERON(R)-TB Gold test as well as a consultation with and clearance by local infectious disease (ID) department b. Levels of serum immunoglobulin G (IgG) \< 3.3g/L c. Estimated glomerular filtration rate (eGFR) \< 60 mL/min/1.73 m2 using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation d. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT)\>= 2.0 x the upper limit of normal (ULN) e. Platelet count \< 100,000 plt/mcL (\< 100 x 10\^9/L) f. Hemoglobin \< 10 g/dL g. Absolute neutrophil count \< 1.5 × 10^9/L h. Absolute lymphocyte count \< 1.2 x 10^9/L 23. Past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements or that may impact the quality or interpretation of the data obtained from the study

Conditions & Interventions

Interventions:
DRUG: Ocrelizumab, DRUG: Placebo for Ocrelizumab
Conditions:
Multiple Sclerosis
Keywords:
Ocrelizumab, Multiple sclerosis, Relapse

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE4
IRB
Number:

Number:
System ID: NCT05285891

Thank you for choosing StudyFinder. Please visit http://studyfinder.cctr.vcu.edu to find a Study which is right for you and contact ctrrecruit@vcu.edu if you have questions or need assistance.