ForPatients
by Roche

Multiple Sclerosis (MS)

A study to compare two different formulations of ocrelizumab given under the skin in participants with multiple sclerosis

A Study to Assess Bioequivalence of Two Subcutaneous (SC) Formulations of Ocrelizumab in Participants With Multiple Sclerosis (MS)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07074886 2024-517980-22-00 CN45320

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 Phase II, Randomized, Open-label, Parallel Group, Multicenter Study to Assess Bioequivalence of Two Subcutaneous Formulations of Ocrelizumab in Patients With Multiple Sclerosis

Trial Summary:

The main purpose of this study is to assess the bioequivalence of ocrelizumab SC test formulation to the marketed ocrelizumab SC reference formulation in participants with either relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS). The study consists of 2 phases: a controlled phase, where participants in each group will receive one dose of test or reference formulation and a continuation phase, where all participants in both groups will receive ocrelizumab SC test formulation.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

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Trial Identifiers

Eligibility Criteria:

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

1. Why is this study needed?

Multiple sclerosis (MS) is a health condition in which the immune system attacks the protective covering of nerve fibres in the brain and spinal cord. This leads to communication problems between the brain and the rest of the body. The immune system is the body's natural defence, which protects the body from foreign or harmful substances such as bacteria and viruses. There are limitations to the available treatments for MS. Sometimes they are not convenient, depending on how often they need to be taken, or the unwanted effects they cause. Some treatments can also take several hours to be given, such as an infusion. More options for how treatment is given are needed.

This study is testing a new formulation of a medicine called ocrelizumab for injection under the skin, which is called a subcutaneous (SC) injection. It is being developed to treat MS.

The new formulation of ocrelizumab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved the new formulation of ocrelizumab for the treatment of multiple sclerosis. The original formulation of ocrelizumab for injection under the skin has been approved by multiple health authorities, including in the United States and Europe.

The purpose of this study is to see how the body responds to two different ocrelizumab formulations for SC injection. We want to compare the new formulation and the original formulation to see:

- If the same amount of drug is taken up by the body
- If it is safe and well tolerated
- How the drug affects the body
- How the immune system reacts to the drug.

2. Who can take part in the study?

People of 18 - 65 years of age with a diagnosis of relapsing MS (RMS) or primary progressive MS (PPMS) can take part in the study.

RMS is known for periods where new or existing symptoms get worse (relapse) followed by a period of recovery (remission). During remission, few symptoms are present. PPMS is where symptoms and disability gradually get worse. There are no periods of relapse or remission.

People may not be able to take part in this study if they have had treatment previously with certain MS medications.

People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take up to 6 weeks before the start of treatment.

Everyone who joins this study will be put into one of two groups randomly (like flipping a coin) for their first treatment at the start of the study. They will be given either the new formulation of ocrelizumab or the original formulation of ocrelizumab. Both formulations will be given as an SC injection. Participants will have an equal chance of being placed in either group.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

After the first treatment, everyone will be given six more treatments with the new formulation of ocrelizumab. These will be given as an SC injection once every 6 months.

The total time of participation in the study will be about 3.5 years. During this study, the study doctor will see participants about 27 times. There are 10 visits in the first month after the first SC injection, and then the visits become less frequent. They will check for any unwanted effects participants may have. Participants will have one follow-up visit 6 months after completing the study treatment, during which the study doctor will check on the participant's well being. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to compare the two formulations of ocrelizumab are the levels of ocrelizumab in the blood. This will be assessed from when the first injection is given until the participant finishes the study. Other key results measured in the study include the number and type of unwanted effects and the results of other safety assessments.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drugs
Participants may have unwanted effects of the drugs used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Ocrelizumab for injection under the skin
Participants will be told about the known unwanted effects of ocrelizumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include: injection reaction (including redness, itching, swelling, headache), respiratory infections (including cold, sinus infection, inflamed tonsils, sore throat, or flu). It could make it harder for the immune system of participants to fight a new infection.

The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Diagnosis of RMS or PPMS according to the revised McDonald 2017 criteria (Thompson et al. 2018) or the most current McDonald criteria at the time of study start
- Expanded Disability Status Scale (EDSS) score, 0-6.5, inclusive, at screening

Exclusion Criteria:

- Participants who have previously received anti-cluster of differentiation (CD)20s (including ocrelizumab) less than 2 years before screening
- Participants who have previously received anti-CD20s (including ocrelizumab) more than 2 years before screening if one of the following conditions is met: B-cell count is below lower limit of normal (LLN), or the discontinuation of the treatment was due to safety reasons
- History of confirmed or suspected progressive multifocal leukoencephalopathy (PML)
- History of cancer, including hematologic malignancy and solid tumors, within 10 years of screening
- Immunocompromised state
- Sensitivity or intolerance to any ingredient (including excipients) of ocrelizumab
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- Significant, uncontrolled disease, such as cardiovascular, pulmonary, renal, hepatic, endocrine or gastrointestinal, or any other significant disease that may preclude participation in the study
- Lack of peripheral venous access
- Previous treatment with cladribine, atacicept, and alemtuzumab
- Any previous treatment with bone marrow transplantation and hematopoietic stem cell transplantation
- Any previous history of transplantation or anti-rejection therapy
- Positive screening tests for active, latent, or inadequately treated hepatitis B virus (HBV)