ForPatients
by Roche

Multiple Sclerosis (MS)Primary Progressive Multiple Sclerosis (PPMS)Relapsing Multiple Sclerosis (RMS)

A clinical trial to examine if an injection of ocrelizumab under the skin is a safe and effective alternative way of treating patients with multiple sclerosis (MS)

A Phase III, Non-Inferiority, Randomized, Open-Label, Parallel Group, Multicenter Study To Investigate The Pharmacokinetics, Pharmacodynamics, Safety And Radiological And Clinical Effects Of Subcutaneous Ocrelizumab Versus Intravenous Ocrelizumab In Patients With Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Completed	8 Countries	NCT05232825 2020-005448-48 CN42097

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 Study To Investigate The Pharmacokinetics, Pharmacodynamics, Safety And Radiological And Clinical Effects Of Subcutaneous Ocrelizumab Versus Intravenous Ocrelizumab In Patients With Multiple Sclerosis

Trial Summary:

This study will evaluate the pharmacokinetics, pharmacodynamics, safety, immunogenicity, and radiological and clinical effects of subcutaneous (SC) administration of ocrelizumab compared with the intravenous (IV) infusion of ocrelizumab in patients with either relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT05232825 2020-005448-48 CN42097
Trial Identifiers

Eligibility Criteria:

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

How does the OCARINA II clinical trial work?

This clinical trial is recruiting people who have a type of disease called multiple sclerosis (MS). In order to take part, patients must have been diagnosed with either primary progressive multiple sclerosis (PPMS) or relapsing multiple sclerosis (RMS).

The purpose of this clinical trial is to examine if an injection of ocrelizumab under the skin is as safe and works as well as an infusion of ocrelizumab into the vein (this is how the treatment is currently given). This clinical trial will also help to understand the way your body processes ocrelizumab injections.

In this clinical trial, you will get either injections of ocrelizumab under the skin or two ocrelizumab infusions into the vein, followed by injections of ocrelizumab under the skin.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be aged 18–65 years old and have been diagnosed with either PPMS or RMS according to specific criteria. You must also have a score of 0–6.5 on the Extended Disability Status Scale (EDSS). If you have an EDSS score of less than 2.0, you must have been diagnosed with MS within the last 15 years. You must also have had stable MS disease for at least 30 days.

You may not be able to take part in this trial if you have a history of certain other medical conditions or have previously received certain treatments. If you are pregnant or breastfeeding, you will not be able to take part in this trial. If you are living in Europe and are planning to become pregnant within a year of your final dose of ocrelizumab, you will not be able to take part. If you are living in the US and are planning to become pregnant within six months of your final dose of ocrelizumab, you will not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, and for up to a year after, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins the clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Ocrelizumab as an injection under the skin every 24 weeks (three injections in total over a treatment period of 48 weeks)
- OR ocrelizumab as two infusions into the vein (two weeks apart), followed by ocrelizumab as an injection under the skin every 24 weeks (two infusions and two injections in total over a treatment period of 48 weeks)

You will have an equal chance of being placed in either group. This is an open-label clinical trial, which means that you will know which group you are in.

Patients in both groups will be given premedication before receiving ocrelizumab, to reduce the risk of side effects. If your doctor thinks it is suitable, a nurse may be able to give you your final injection of ocrelizumab in your own home.

Patients in both groups will be monitored throughout the clinical trial to see how the treatment is affecting the body and to check for any side effects. This will include additional hospital visits for MRI scans. Your doctor may also see you to carry out other checks, such as blood tests or testing of your mobility and function.

How long will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment for 48 weeks. You are free to stop this treatment at any time.

After finishing treatment, you will still be seen regularly by the clinical trial doctor, every 24 weeks until 48 weeks after your last dose of clinical trial treatment. These hospital visits will include checks to see how you responded to the treatment and any side effects that you may be having.

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What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05232825

Trial-identifier: NCT05232825

Inclusion Criteria:

- Diagnosis of PPMS or RMS according to the revised McDonald 2017 criteria (Thompson et al. 2018)
- EDSS score, 0-6.5, inclusive, at screening
- Neurological stability for #30 days prior to both screening and baseline
- Disease duration from onset of MS symptoms of less than 15 years for patients with EDSS score <2.0 at screening
- For females participants, without reproductive potential may be enrolled if post-menopausal, unless receiving a hormonal therapy for menopause or if surgically sterile
- For females of childbearing potential, agreement to remain abstinent or use adequate contraceptive methods

Exclusion Criteria:

- Any known or suspected active infection at screening or baseline (except nailbed infections), or any major episode of infection requiring hospitalization or treatment with IV anti microbials within 8 weeks prior to and during screening or treatment with oral anti microbials within 2 weeks prior to and during screening
- 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
- Receipt of a live-attenuated vaccine within 6 weeks prior to randomization Influenza vaccination is permitted if the inactivated vaccine formulation is administered
- Inability to complete an MRI or contraindication to gadolinium administration
- Contraindications to mandatory premedications for IRRs, including closed-angle glaucoma for antihistamines
- Known presence of other neurologic disorders
- 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 patient from participating in the study
- History of or currently active primary or secondary (non-drug-related) immunodeficiency
- Pregnant or breastfeeding, or intending to become pregnant during the study and 6 or 12 months
- Lack of peripheral venous access
- History of alcohol or other drug abuse within 12 months prior to screening

- Treatment with any investigational agent within 24 weeks prior to screening or 5 half-lives of the investigational drug (whichever is longer), or treatment with any experimental procedure for MS (e.g., treatment for chronic cerebrospinal venous insufficiency)
- Participants who have previously received anti-CD20s if the last treatment was less than 2 years before screening, and/or if B-cell count is below lower limit of normal, and/or the discontinuation of the treatment was due to safety reasons or lack of efficacy
- Previous treatment with cladribine, atacicept, and alemtuzumab
- Previous treatment with fingolimod, siponimod, ponesimod, or ozanimod within 6 weeks of baseline
- Previous treatment with interferons beta (1a or 1b), or glatiramer acetate within 2 weeks of baseline
- Previous treatment with natalizumab within 4.5 months of baseline
- Treatment with mitoxantrone within 2 years prior to baseline visit or evidence of cardiotoxicity following mitoxantrone use or a cumulative lifetime dose of more than 60 mg/m2
- Previous treatment with any other immunomodulatory or immunosuppressive medication not already listed above without appropriate washout as described in the applicable local label.
- If the washout requirements are not described in the applicable local label, then the wash out period must be 5 times the half-life of the medication. The PD effects of the previous medication must also be considered when determining the required time for washout.
- Any previous treatment with bone marrow transplantation and hematopoietic stem cell transplantation
- Any previous history of transplantation or anti-rejection therapy
- Treatment with IV Ig or plasmapheresis within 12 weeks prior to randomization
- Systemic corticosteroid therapy within 4 weeks prior to screening
- Positive screening tests for active, latent, or inadequately treated hepatitis B
- Sensitivity or intolerance to any ingredient (including excipients) of ocrelizumab
- Any additional exclusionary criterion as per ocrelizumab (Ocrevus®) local label, if more stringent than the above