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 source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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).

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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.

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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.

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.

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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

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