ForPatients
by Roche

Multiple Sclerosis (MS) Progressive Multiple Sclerosis (PMS)

A Clinical Trial of Ocrelizumab in Patients with Progressive Multiple Sclerosis (CONSONANCE)

A Study to Evaluate Ocrelizumab Treatment in Participants With Progressive Multiple Sclerosis (CONSONANCE)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT03523858 2017-001313-93,2023-506429-13-00 MN39159

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 is a prospective, multicenter, open-label, single-arm effectiveness and safety study in participants with progressive multiple sclerosis (PMS).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03523858 2017-001313-93,2023-506429-13-00 MN39159
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 65 Years	No

How does the CONSONANCE clinical trial work?

This clinical trial is recruiting people who have a progressive form of ‘multiple sclerosis’ or MS, which is a disabling disease of the brain and spinal cord.

The aim of this clinical trial is to see if the trial medicine, ocrelizumab, will stop the signs and symptoms of your progressive form of MS from getting worse.

How do I take part in this clinical trial?

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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 who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

If you agree to take part in the clinical trial, 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 and procedures may be part of your regular medical care and 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 and what other treatments are available so that you may decide if you still want to take part.

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

Everyone who joins this clinical trial will be given the treatment ocrelizumab into their vein (this is called an ‘intravenous infusion’).

Patients will also be given two additional medicines, one called methylprednisolone and an antihistamine drug, about 30–60 minutes before the start of the ocrelizumab. Your doctor might also give you other medicines such as acetaminophen/paracetamol before the ocrelizumab. You will be given the first two doses of ocrelizumab on Day 1 and Day 14 of the clinical trial, and then another dose every 6 months after that for up to about 3 years.

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

During this clinical trial, you will have 11 visits at the clinical trial site, including the screening visit. At every visit, you will need to stay at the clinical trial site for at least 1 hour after the ocrelizumab infusion has finished. You will also need to come to a follow-up visit around 12 months after your last infusion to check on any side effects. At your final clinical trial visit, if you and your doctor decide to continue your treatment, you may be able to move onto another Roche clinical trial or continue with ocrelizumab.

Your total time in the clinical trial will be about 5 years. You can leave the clinical trial at any time. If you decide to no longer take part in the clinical trial, you will need to return to the clinical trial site for at least 12 months, to check that you are not having any side effects.

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What happens if I’m 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 treatments for you that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03523858

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