ForPatients

by Roche

Multiple Sclerosis (MS)

A study of ocrelizumab in patients with multiple sclerosis (MuSicalE)

Non-interventional Study of Ocrelizumab in Participants With Relapsing or Primary Progressive Multiple Sclerosis (MuSicalE)

Trial Status Trial Runs In Trial Identifier
Active, not recruiting 23 Countries NCT03593590 MN39889

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 is a multicentre non-interventional study aimed at evaluating the real-world effectiveness and safety of ocrelizumab treatment in participants with relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS), who have been prescribed ocrelizumab as per routine practice. This study will use a comprehensive combination of participant reported outcomes and conventional multiple sclerosis (MS) endpoints that measure clinical domains commonly affected by MS (e.g. fatigue, hand function, gait, cognition), and their impact on employment, activities of daily living, quality of life and healthcare resource utilization. The incidence, type, and pattern of serious adverse events (SAEs), and of adverse events (AEs) leading to treatment discontinuation will also be determined.

Hoffmann-La Roche Sponsor		N/A Phase	
NCT03593590 MN39889 Trial Identifiers			
Eligibility Criteria:			
Gender All	Age >= 18 Years		Healthy Volunteers No

How does the MuSicalE study work? This study is recruiting people who have different types of multiple sclerosis. The study will include patients whose doctor has decided to prescribe a treatment called ocrelizumab for their multiple sclerosis.

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How do I take part in this study? To be able to take part in this study, your doctor must have decided to prescribe ocrelizumab for your multiple sclerosis, and you must not have received ocrelizumab before.

If your doctor thinks that you might be able to take part in this study, he/she will give you all the information you need to make your decision about taking part in the study.

What treatment will I be given if I join this study? Everyone who joins this study will receive ocrelizumab.

 Ocrelizumab will be given into your vein (called an intravenous infusion), first as two separate doses given 2 weeks apart, and then once every 6 months for at least 4 years.

If your doctor recommends that you are treated with ocrelizumab, you will still receive this treatment even if you decide not to take part in this study.

How often will I be seen in follow-up appointments, and for how long? In this study, you will be given ocrelizumab every 6 months for 4 years. You will be followed up for assessment of the effectiveness and safety of ocrelizumab depending on the guidelines for your local area. Some of the assessments require you to answer questionnaires, at home or in the hospital, before your ocrelizumab infusion. You are free to stop this treatment at any time.

Your care and treatment will be determined by your doctor, and information for this study will be collected from assessments and tests that your doctor carries out at each visit, which will be scheduled once every 6 months.

What happens if I'm unable to take part in this study? If your specific type of multiple sclerosis does not match what this study is looking at or you have previously received ocrelizumab you will not be able to take part in this study. You will still be able to receive ocrelizumab as prescribed by your doctor. You will not lose access to any of your regular care.

For more information about this study see the **For Expert** tab on this page or follow this link to <u>ClinicalTrials.gov</u>

Trial-identifier: NCT03593590