ForPatients
by Roche

Multiple Sclerosis (MS)

A rollover study to evaluate the long-term safety and efficacy of ocrelizumab in patients with multiple sclerosis

A Rollover Study to Evaluate the Long-Term Safety and Efficacy of Ocrelizumab In Patients With Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	37 Countries	NCT05269004 2023-505974-14-00 MN43964

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 Phase IIIb, single-arm, multicenter, OLE study. Participants receiving ocrelizumab as an investigational medicinal product (IMP) in a Roche sponsored Parent study who continue to receive ocrelizumab or are in safety follow-up at the time of the closure of their respective Parent study (WA21092, WA21093 or WA25046) are eligible for enrollment in this extension study. Participants who will continue ocrelizumab treatment will receive IMP based on the dosage and administration received at the time of rollover from the Parent study.

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

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Multiple sclerosis (MS) is a long-lasting health condition in which the body's natural defence (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. People with MS may have mental processes (cognitive) problems, and other symptoms such as sexual problems, speech problems, muscle weakness or numbness,

lack of balance and coordination. In relapsing MS (RMS), the signs or symptoms of MS return after they have improved for a while. This is known as a relapse. When MS gradually worsens without any periods of improvement in symptoms, it is called primary progressive multiple sclerosis (PPMS). Currently, there are no drugs to cure MS, however, treatments for MS include drugs that try to prevent the immune system from attacking the nerves. This study is testing a medicine called ocrelizumab. It has already been approved by health authorities worldwide for the treatment of RMS and PPMS. However, it is being developed further to optimise its use in MS.

This study aims to learn about the long-term safety and effectiveness of ocrelizumab in people with MS who had been receiving ocrelizumab in previous studies.

2. Who could take part in the study?

People aged 18 years and older with RMS or PPMS who have completed participating in the previous studies (parent studies) WA21092, WA21093 or WA25046 could take part in this study.

Women who were pregnant, or breastfeeding could not enrol in the study.

3. How does this study work?

People were screened to check if they were able to participate in the study. This screening for participation was done during the last visit in their parent study or a separate visit before receiving treatment in this study.

Participants continuing treatment in this study are receiving ocrelizumab as a drip into the vein (infusion) every 24 weeks. Treatment may continue as long as benefits for the participants are higher than any unwanted effects they may experience.

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.

During the study, the study doctor examines the participants every 24 weeks to see how well the treatment is working and any unwanted effects participants may have. In between study visits, participants may receive a telephone call from the study doctor to check on their general well-being. After completion of treatment, the participants will have a safety follow-up period of 48 weeks. Participants who completed ocrelizumab treatment and had entered the safety follow-up in the parent study will continue their safety follow-up in this study, completing a total of 48 weeks.

Total time of participation in the study will be about 6.5 years up to a maximum of 8 years. 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 are to find out the number of participants with unwanted effects, serious unwanted effects and to collect information on types of unwanted effects.

Other key results measured in the study include:

- Assessing how the participant's disability changes over time using a special scale called the Expanded Disability Status Scale (EDSS).
- Assessing how a participant's ability to use their arms and legs changes over time. This will be measured using two special scales: the 9-Hole Peg Test (9HPT) for checking how well the participant can use their hands and the Timed 25-Foot Walk Test (T25FWT) to check their walking ability.
- Number and amount of new or enlarging spots of tissue injury/damage (lesions) in the brain and assessing how that amount changes over time, measured by magnetic resonance imaging (MRI). MRI is a test used to take pictures of organs like the brain.

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 were informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study were 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 are having regular check-ups, every 24 weeks to see if there are any unwanted effects.

Ocrelizumab Participants were 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 an infection of the nose, throat, or sinuses, usually caused by a virus (upper respiratory tract infection), flu (influenza), sore throat and runny nose (nasopharyngitis), and decrease in blood immunoglobulins (specially types M and G) which are proteins that protects the body from infection.

In this study, ocrelizumab is being given as a drip into a vein. Known unwanted effects with infusion include irritation where the injection is given, fever, chills, swelling, rash, redness, itching, or pain.

The study medicines may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.