ForPatients
by Roche

Multiple Sclerosis (MS)

A clinical extension trial to look at how well and safe ocrelizumab works long-term in people with multiple sclerosis who benefitted from ocrelizumab in a previous F. Hoffmann-La Roche Ltd sponsored trial

This is an Extension Study of the Roche P-trials to Investigate Safety and Effectiveness of Ocrelizumab in Participants With Multiple Sclerosis (MS)

Trial Status	Trial Runs In	Trial Identifier
Completed	26 Countries	NCT03599245 2017-004886-29 2017 MN39158

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Single Arm, Open Label Multicentre Extension Study To Evaluate The Effectiveness And Safety Of Ocrelizumab In Patients With Multiple Sclerosis Previously Enrolled In A F. Hoffmann-La Roche Sponsored Ocrelizumab Phase IIIb/IV Clinical Trials

Trial Summary:

This extension study will evaluate the effectiveness and safety of ocrelizumab in multiple sclerosis (MS) participants who were previously enrolled in a F. Hoffmann-La Roche (Roche) sponsored ocrelizumab phase IIIb/IV trial (i.e. the Parent, P-trial).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03599245 2017-004886-29 2017 MN39158
Trial Identifiers

Eligibility Criteria:

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

1. Why is the LIBERTO clinical trial needed?

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Multiple sclerosis (MS) is a condition where the immune system attacks myelin, the protective layer around nerve fibres. This makes it difficult for the brain to send signals to the rest of the body. MS can cause many symptoms including pain, tiredness, vision problems, sleep disorders and problems with walking or balance. Most people experience relapsing-remitting MS and have periods with attacks of new or worsening symptoms, known as ‘relapses’, divided by periods of partial recovery. In some people with relapsing-remitting MS, disease modifying treatment is not always effective in preventing new symptoms and stopping physical ability from getting worse. This clinical trial aims to look at how well ocrelizumab works and how safe it is long-term in people with MS.

2. How does the LIBERTO clinical trial work?

People can take part if they have relapsing-remitting MS and were previously treated in an ocrelizumab-based clinical trial sponsored by F. Hoffmann-La Roche Ltd (called the ‘parent trial’). The participant’s neurologist must also agree that the benefits to continuing treatment outweigh any risks.

People who take part in this clinical trial (participants) will be given the clinical trial treatment ocrelizumab for up to 18 months. The clinical trial doctor will see them every 6 months. These hospital visits will include checks to see how the participant responds to the treatment and checks for any side effects (an unwanted effect of a drug or medical treatment) they may have. After the last dose of ocrelizumab, participants may see the clinical trial doctor once or twice over the next year for final safety checks. The total time of participation in the clinical trial can be a maximum of 2 and a half years, including final safety checks. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the LIBERTO clinical trial?

The main clinical trial endpoint (the main results measured in the trial) is to look at how well ocrelizumab works since starting treatment in the parent trial. This is measured by:

- The number of participants whose physical ability improves or worsens or stays the same and how big these changes are
- The amount of time before physical ability first worsens in participants with worsening physical ability that lasts for at least 6 months or 1 year
- The number of participants with worsened walking speed and/or hand control, and the time taken to reach a certain level of worsening
- The number of participants who have no relapses
- The number of participants with no disease activity (who have no relapses, no worsening of physical ability that lasts for at least 6 months and no new or growing brain lesions) and/or have no worsening of physical ability, walking speed and hand control that lasts for at least 6 months
- The amount of time before ocrelizumab treatment is stopped

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- The amount of time before a relapse, physical ability first worsens lasting for at least 6 months, or new or growing brain lesions first appear
- The number of relapses that participants have per year
- Change in thinking/reasoning
- Changes detected by brain scans (magnetic resonance imaging, or MRI)
- Changes in ability to do paid work, symptoms and quality of life

The other clinical trial endpoints include:

- the type, number and seriousness of side effects and,
- any changes in other medicines that the participant is taking during the trial for any reason.

4. Who can take part in this clinical trial?

People can take part in this trial if they have relapsing-remitting MS and have benefitted from ocrelizumab treatment given in the parent trial. If the participant can become pregnant, they must use a reliable method of birth control during the treatment and for at least 6 months after the last dose of ocrelizumab.

People may not be able to take part in this trial if they have stopped the clinical trial treatment in the parent trial or if they have been given certain other treatments (such as treatments that suppress the immune system). People cannot take part if the clinical trial treatment has caused serious side effects before or they have a severely weakened immune system.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will continue to be given ocrelizumab as an infusion (into the vein) every 6 months with the last infusion at 18 months. This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

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Risks associated with the clinical trial drug Participants may have side effects from the drug used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; and safety assessments will be performed regularly.

Ocrelizumab Ocrelizumab will be given as an infusion into the vein. Participants will be told about any known side effects of infusions into the vein.

Potential benefits associated with the clinical trial Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

Inclusion Criteria:

- Signed Informed Consent Form
- Able to comply with the study protocol, in the investigator's judgment
- Completed the treatment period of Roche sponsored ocrelizumab P-trials

Exclusion Criteria:

- Hypersensitivity to ocrelizumab or to any of its excipients.
- Participantss in a severely immunocompromised state until the condition resolves.
- Evidence of any adverse event potentially attributable to ocrelizumab, for which the local label recommends permanent discontinuation.
- Existence of a contra-indication as per SmPC
- Prohibited concomitant medication as specified in protocol
- Participants intending to become pregnant during the study or within 6 months after the last dose of the study drug in the parent study

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