ForPatients
by Roche

Multiple Sclerosis (MS)

Study of an on-body injection system for home use of ocrelizumab in people with multiple sclerosis

A phase III, open-label, single-arm, multi#center study to evaluate the safety and use of an on#body delivery system for the subcutaneous home administration of ocrelizumab in patients with multiple sclerosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting		2025-523726-40-00 07617792 CN46182

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A phase III, open-label, single-arm, multi#center study to evaluate the safety and use of an on#body delivery system for the subcutaneous home administration of ocrelizumab in patients with multiple sclerosis

Trial Summary:

Study CN46182 is testing a new formulation of a medicine called ocrelizumab and a new way to give it as an injection into the belly. It is being developed to treat multiple sclerosis (MS). Ocrelizumab is approved for the treatment of MS as a drip into a vein (intravenous infusion) or as an injection under the skin (subcutaneous injection). In this study, a new formulation for injection under the skin will be tested. This new formulation of ocrelizumab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved the new formulation of ocrelizumab for the treatment of multiple sclerosis.

This study aims to see if people with MS or their caregivers can safely administer ocrelizumab using an on-body delivery system (OBDS). The subcutaneous injection will be administered into the belly area.

F. Hoffmann-La Roche Ltd Sponsor	**Phase III** Phase

2025-523726-40-00 07617792 CN46182
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
Males and Females	18 - 65 years	No

1. Why is this study needed?

Multiple sclerosis (MS) is a health condition in which the 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. The immune system is the body's natural defence, which protects the body from foreign or harmful substances such as bacteria and viruses. MS can be relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS). RMS is known for periods where new or existing symptoms get worse (relapse) followed by a period of partial or complete recovery (remission). During remission, a few symptoms may be present. PPMS is where symptoms and disability gradually get worse. There are no periods of relapse or remission.

There are limitations to the available treatments for MS. Sometimes, they are not convenient, depending on how often they need to be taken or where the treatment is administered. For example, some treatments can take several hours to be given, such as an infusion. More options for how treatment is given are needed.

This study is testing a new formulation of a medicine called ocrelizumab and a new way to give it as an injection into the belly. It is being developed to treat MS.

Ocrelizumab is approved for the treatment of MS as a drip into a vein (intravenous infusion) or as an injection under the skin (subcutaneous injection). In this study, a new formulation for injection under the skin will be tested. This new formulation of ocrelizumab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved the new formulation of ocrelizumab for the treatment of multiple sclerosis.

This study aims to see if people with MS or their caregivers can safely administer ocrelizumab at home using an on-body delivery system (OBDS). The subcutaneous injection will be administered into the belly area.

2. Who can take part in the study?

People (males/females) of 18-65 years of age with MS can take part in the study if they are already being treated with ocrelizumab and are willing to complete the injections, which can be administered by themselves or by a caregiver.

People may not be able to take part in this study if they do not have regular access to a phone. Because this study involves taking medication at home, participants should live in an area with easy access to medical services if needed. People who are pregnant, planning to become pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place up to 4 weeks before the start of treatment.

Everyone who joins this study will receive the new formulation of ocrelizumab using an OBDS every 6 months, as described below:

- The first few participants will complete their first injection at the clinic before home administration is allowed for any participants in the study. This is to make sure that it is safe for all participants or their caregivers to complete the injection at home. If home administration is allowed, the participants who did their first injection at the clinic or their caregivers will complete subsequent injections at home.
- The rest of the participants or their caregivers will complete all injections at home.

This is an open-label study. This means everyone involved, including the participant, their caregiver, and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants every 6 months. They will check for any unwanted effects participants may have. They will also receive follow-up telephone calls and visits from the study doctor to check on their well-being after the at-home injection. Participants will also have a follow-up visit after 6 months of completing the study treatment, during which the study doctor will check on the participant's well-being. Total time of participation in the study will be about 1.5 years. Participants have the right to stop study treatment and leave the study at any time.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are the number of participants who are able to complete their first injection using the OBDS, either by themselves or by a caregiver.

Other key results measured in the study include the number and type of unwanted effects and the results of other safety assessments.

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 will be informed about the risks

and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other treatment options.

Risks associated with the study medicines and devices
Participants may have unwanted effects of the medicines and devices 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 will have regular check-ups to see if there are any unwanted effects.

Ocrelizumab for injection under the skin Participants will be 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 injection reactions (including redness, itching, swelling, headache), and respiratory infections (including cold, sinus infection, inflammation in the tonsils, sore throat, or flu). It could make it harder for the immune system of participants to fight a new infection.

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

OBDS
Participants will be told about any known unwanted effects of the OBDS, and where relevant, also potential unwanted effects based on human and laboratory studies or knowledge of similar devices.