

Progressive Multiple Sclerosis (PMS)

A study to compare different doses of RO7268489 with a placebo, as add-on therapy to ocrelizumab, in people with multiple sclerosis that has progressed

A Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of RO7268489 as Add-on Therapy to Ocrelizumab, in Participants With Progressive Forms of Multiple Sclerosis (MS)

Trial Status
Recruiting

Trial Runs In
11 Countries

Trial Identifier
NCT07282574 2025-521636-10-00
BP46016

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

The main purpose of this study is to assess the efficacy of RO7268489 in adults with progressive multiple sclerosis (PMS) receiving ocrelizumab. After the end of the double-blind period, an open-label (OL) extension may allow eligible participants to receive open-label RO7268489.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07282574 2025-521636-10-00 BP46016
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
>=18 Years & <= 60 Years

Healthy Volunteers
No

1. Why is this study needed?

Multiple sclerosis (MS) is a long-lasting disease that affects the central nervous system, which includes the brain and spinal cord. It causes the immune system to attack the protective covering of nerve fibers, leading to communication problems between the brain and the rest of the body. Symptoms can vary widely and may include vision problems,

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difficulty walking, muscle weakness, numbness, pain, and fatigue. MS often starts in young adults and can lead to increasing disability over time.

This study is testing a medicine called RO7268489. It is being developed to treat MS that has progressed (worsened).

RO7268489 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7268489 alone (or in combination with any other drug) for the treatment of MS.

This study aims to compare the effects of RO7268489 against a placebo (a non-active pill or “sugar pill”) in people with progressive forms of MS. In addition to RO7268489 or placebo, everyone in the study will receive ocrelizumab, a drug which is already approved for the treatment of MS.

2. Who can take part in the study?

People aged 18 - 60 years with MS that has progressed can take part in the study if they are able and willing to provide informed consent, if they do not need a wheelchair but have at least moderate disability walking, have documented evidence of disability progression over the past 2 years, and agree to wear a digital device to see how well they walk.

People will not be able to take part in this study if they are pregnant, breastfeeding, or planning to become pregnant during the study. They also cannot participate if they have had a recent MS relapse, certain infections, a history of cancer, or certain immune system problems. Other reasons for exclusion include severe heart, liver, or kidney issues, a history of severe allergic reactions, or use of certain medications or substances like cannabis or THC. Additionally, people with certain serious psychiatric conditions, a history of alcohol or drug abuse, people who are currently participating in another study or those who cannot undergo an MRI will also be excluded.

3. How does this study work?

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

Everyone who joins this study will receive ocrelizumab as infusions in a vein once every 6 months (in the same way that ocrelizumab is approved by health authorities). In addition, everyone who joins the study will be split into 4 groups randomly. Participants will have a one in four chance of being placed in any group. Depending on the group they are in, people will receive low, middle or high doses of RO7268489, given as capsules every day, OR placebo, also given as capsules every day.

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This is a 'placebo-controlled' study. This means that participants are put in a group that will receive RO7268489 or a group that will receive 'placebo' (a medicine that contains no active ingredients but looks the same as the study medicine). Comparing results from the different groups helps researchers know if any changes seen are caused by RO7268489 or occur by chance.

This is a double-blind study. This means that neither the people in the study nor the team running it will know whether they receive a certain dose of RO7268489 or a placebo until the study is over. This is done to make sure that the results of the treatment are not affected by what people expect from the treatment they receive. However, the study doctor can find out which group a participant is in, if the participant's safety is at risk.

During this study, the study doctor will see participants regularly. They will check how well the treatment is working and ask about any unwanted effects people may have. Participants will have follow-up visits until 20 weeks after completing RO7268489 or placebo treatment, during which the study doctor will check on the participant's well-being. At the end of the study, they will also have follow-up visits until 48 weeks after their last study dose of ocrelizumab treatment. Total time of participation in the study will be about 3 to 5 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 to assess if the medicine has worked are how well people can walk (with the 25-foot walk test and the expanded disability status scale) and use their hands (with the 9-hole peg test). Other key results measured in the study include how easily the brain can process information, how RO7268489 is processed by the body, how well people feel, as well as MS-related changes in brain and spine measures (with MRI imaging) and in blood.

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. However, the information collected in the study may help other people with MS or similar 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. 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 options of treatment.

Risks associated with the study Participants may have unwanted effects of the drugs used in the 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

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to see if there are any unwanted effects and can contact their study doctor at any time to let them know about any symptoms, they experience that may be unwanted effects.

RO7268489 Participants will be told about the known possible unwanted effects of RO7268489, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include anxiety or panic attacks, trouble speaking, and changes in mood or emotion as well as feeling sleepy or tired, headache, and nausea.

Ocrelizumab

Participants will be told about the known possible unwanted effects of ocrelizumab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include infusion-related reactions, infections affecting the nose and throat, and decreased levels of special blood proteins which help protect against infection.

Ocrelizumab will be given through a needle placed in a vein. Known unwanted effects may include mild discomfort during the procedure, bruising, and infection at the needle site.

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