ForPatients
by Roche

Multiple Sclerosis (MS) Primary Progressive Multiple Sclerosis (PPMS)

A clinical trial to compare fenebrutinib with ocrelizumab in people with primary progressive multiple sclerosis (PPMS)

A Study To Evaluate The Efficacy And Safety Of Fenebrutinib Compared With Ocrelizumab In Adult Participants With Primary Progressive Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	29 Countries	NCT04544449 2019-003919-53 GN41791

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

Trial Summary:

A study to evaluate the efficacy and safety of fenebrutinib on disability progression in adult participants with Primary Progressive Multiple Sclerosis (PPMS). All eligible participants will be randomized 1:1 to either daily oral fenebrutinib (and placebo) or intravenous (IV) ocrelizumab (and placebo) in a blinded fashion through an interactive voice or web-based response system (IxRS). Approximately 946 participants will be enrolled and will be recruited globally. Participants who discontinue study medication early or discontinue from the study will not be replaced. The Open-Label Extension (OLE) phase is contingent on a positive benefit-risk result in the Primary Analysis of the study.

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

NCT04544449 2019-003919-53 GN41791
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 65 Years	No

How does the GN41791 clinical trial work?

This clinical trial is recruiting people who have a type of disease called primary progressive multiple sclerosis (PPMS).

The purpose of this clinical trial is to compare the effects, good or bad, of fenebrutinib against ocrelizumab in patients diagnosed with PPMS. If you take part in this clinical trial, you will receive either fenebrutinib or ocrelizumab.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be aged 18–65 years old and have been diagnosed with PPMS according to specific criteria. You must also have a score of 3.0–6.5 on the Extended Disability Status Scale (EDSS), be able to complete the 9-hole peg test (a hand function test) with each hand in less than 240 seconds (four minutes) and be able to complete the timed 25-foot walk test (a test of your ability to walk without assistance).

You may not be able to take part in this clinical trial if you have a history of certain other medical conditions or have previously received certain treatments.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- fenebrutinib in the form of two pills twice a day, as well as a dummy treatment that is given like ocrelizumab (an infusion into the vein, containing no active ingredients, every 24 weeks)

- OR ocrelizumab as an infusion into the vein every 24 weeks, as well as a dummy treatment that is given like fenebrutinib (two pills, containing no active ingredients, twice a day)

You will have a 1 in 2 chance of being placed in either group.

This is a ‘double-dummy’ clinical trial, which means that both groups will be given treatments that look exactly the same. Dummy treatments are used so that doctors and patients cannot work out which treatment each group is receiving.

This part of the trial is called the double-blind treatment (DBT) phase. Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment fenebrutinib or ocrelizumab for a minimum of 120 weeks in the DBT phase. You are free to stop this treatment at any time but you may continue to have follow-up appointments for safety reasons. You will still be seen regularly by the clinical trial doctor roughly every six weeks during the first 24 weeks and every 12 weeks for the remainder of the 120 weeks. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

Once the first part of the trial is complete, you may be given the option to take part in a further open-label extension (OLE) part of the trial. All patients who take part in the OLE will receive fenebrutinib as two pills twice a day for 96 weeks. This part of the trial will not be blinded: the patients know that they are getting fenebrutinib, as do the clinical trial doctors.

If you were given ocrelizumab in the DBT phase, you will not be able to start the OLE for at least 24 weeks after your last infusion of ocrelizumab – this is to make sure that clinical trial doctors are only measuring the effects of fenebrutinib in the OLE.

As part of the OLE, you will still be seen regularly by the clinical trial doctor. If you received fenebrutinib in the DBT phase, you will be seen roughly every 12 weeks. If you received ocrelizumab in the DBT phase, you will be seen roughly every six weeks for the first 24 weeks and every 12 weeks for the remainder of the OLE. As in the first part of the trial, these visits will include checks to see how you are responding to treatment and any side effects that you may be having.

If you do not want to take part in the OLE, clinical trial doctors will continue to have check-ups with you roughly every three months for a further 48 weeks after you finish taking your study treatment.

What happens if I am unable to take part in this clinical trial?

ForPatients
by Roche

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the For Expert tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04544449