ForPatients
by Roche

Multiple Sclerosis (MS) Relapsing Multiple Sclerosis (RMS)

A clinical trial to compare fenebrutinib with teriflunomide in people with relapsing multiple sclerosis (RMS)

A Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared With Teriflunomide in Relapsing Multiple Sclerosis (RMS)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	22 Countries	NCT04586010 2019-004857-10,2022-502609-14-00 GN41851

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 and relapse rate in adult participants with RMS. Eligible participants will be randomized 1:1 to either fenebrutinib or teriflunomide. 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

NCT04586010 2019-004857-10,2022-502609-14-00 GN41851
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 55 Years	No

How does the FENhance 1 (GN41851) clinical trial work?

This clinical trial is recruiting people who have a type of disease called relapsing multiple sclerosis (RMS).

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

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How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be aged 18–55 years old and have been diagnosed with RMS according to specific criteria. You must also have scored no more than 5.5 on the Extended Disability Status Scale (EDSS), be able to complete the 9-hole peg test with each hand in less than 4 minutes and be able to complete the timed 25-foot walk test.

You will not be able to take part in this study if you have primary progressive MS (PPMS) or non-active secondary progressive MS (SPMS). You may also be unable to take part if you 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 measures 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 one teriflunomide ‘dummy’ pill that is taken once a day
- OR teriflunomide in the form of a pill once a day, as well as four fenebrutinib ‘dummy’ pills that are taken as two pills twice a day

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

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

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 teriflunomide for up to roughly three and a half years. Your time in the study will depend on how long it takes for every patient to be given study treatment for a minimum period of time and how long it takes for a certain number of patients to experience disease progression. You are free to stop this treatment at any time.

After being given treatment, you will still be seen regularly by the clinical trial doctor about every four weeks in the first six months and then every 12 weeks for the remainder of this time. These visits will include checks to see how you are responding to 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 double dummy; the patients will know that they are getting fenebrutinib, as will the clinical trial doctors.

As part of the OLE, you will still be seen regularly by the clinical trial doctor approximately every 12 weeks. As in the first part of the trial, these visits will also 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 perform regular checks with you for a further eight weeks after you finish taking your study treatment.

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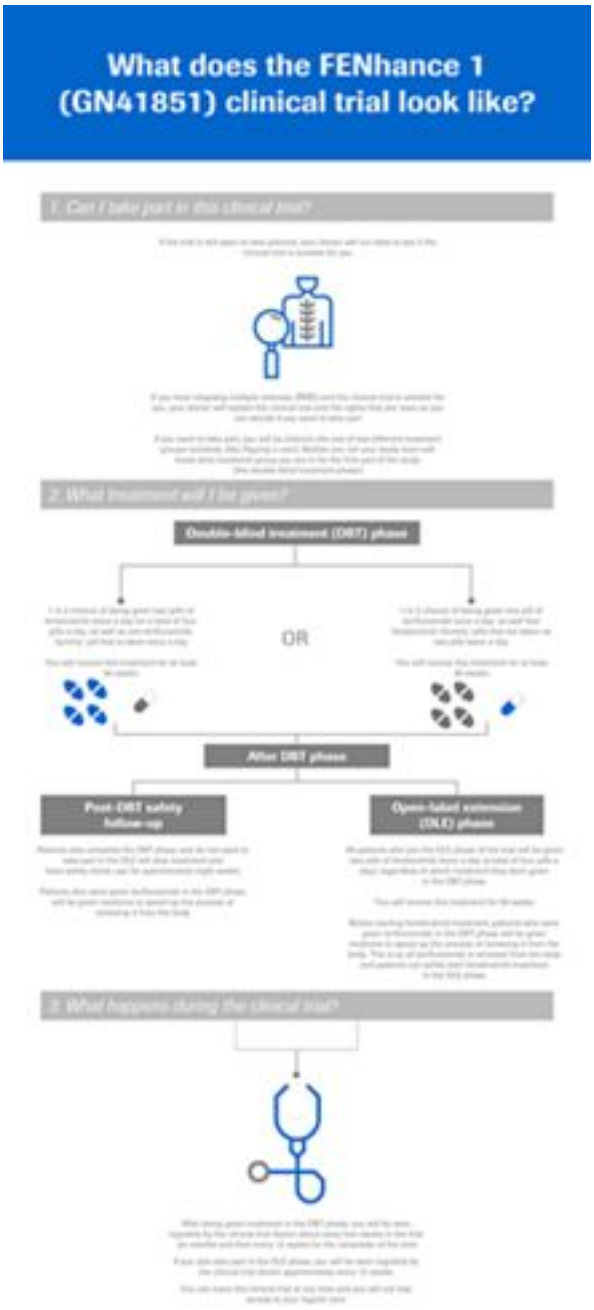

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What happens if I am unable to take part in this clinical trial?

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: https://clinicaltrials.gov/ct2/show/NCT04586010

Trial-identifier: NCT04586010

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