ForPatients
*by Roche*

Multiple Sclerosis (MS) Relapsing Multiple Sclerosis (RMS)

# A study to evaluate the efficacy and safety of fenebrutinib compared with teriflunomide in adult patients with relapsing multiple sclerosis (FENhance 1)

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 | 23 Countries | NCT04586010<br>2019-004857-10,2022-502609-14-00<br>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 | Phase 3 |
|---|---|
| Sponsor | Phase |

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

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | >=18 Years & <= 55 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.

This study is testing a medicine called fenebrutinib. It is being developed to treat relapsing MS. A relapse is the return of signs or symptoms of a disease after they have improved for a while. Fenebrutinib is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved fenebrutinib for the treatment of relapsing MS. Teriflunomide is approved for treating relapsing MS.

This study aims to compare the effects of fenebrutinib versus teriflunomide in people with relapsing MS.

**2. Who can take part in the study?**

People of 18 to 55 years of age with relapsing MS can take part in the study. They must have a score on the Expanded Disability Status Scale (EDSS) of no more than 5.5. The EDSS measures changes in a person's disability level over time. People with an EDSS score of 5.5 or less can walk 100 metres without the use of walking aids or needing to rest.

People who take part in the study must also have had either:

- 2 relapses in the last 2 years
- 1 relapse in the last year, OR
- At least 1 area of inflammation in the brain – known as an 'active lesion' – in the last year

People may not be able to take part in this study if their symptoms of MS have been very mild for more than 10 years. People with a type of MS called 'primary progressive MS', or people who have had certain treatments cannot take part. People also cannot join the study if they have certain infections, a history of cancer, or other conditions including a disease of the brain or spinal cord. People who are 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 can start up to 6 weeks before the start of treatment.

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. Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will be placed into 1 of 2 groups randomly (like flipping a coin) and given either:

- Fenebrutinib pills taken twice a day, as well as a teriflunomide "dummy" pill taken once a day, OR
- Teriflunomide pill taken once a day, as well as fenebrutinib "dummy" pills that are taken twice every day.

Participants will have an equal chance of being placed in either group. A similar number of people will be in each group.

The first part of this study is ‘double-blind’. This means that neither the participants in the study nor the team running it will know which treatment is being given until the double-blind period is over. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

The study doctor will see participants every 2 weeks until Week 20, at Week 24 (6 months), then every 3 months during the double-blind period. They will see how well the treatment is working and any unwanted effects participants may have. The double-blind period will continue for all participants until every participant is seen for nearly 2 years.

After the double-blind period, participants will be given the choice to either stop study treatment or be given ‘open-label’ fenebrutinib. Open-label means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given. The study doctor and the participant will decide together if open-label fenebrutinib should be given if the study doctor believes a participant could benefit from it, and depending on symptoms.

Participants will have a follow-up visit 2 months after completing double-blind or open-label 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 4 and a half years or 6 and a half years, depending on when they join the study and if they have open-label treatment. 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 result measured in the study to assess how well each of the medicines have worked is the number of relapses that participants have per year.

Other key results measured in the study include:

- The amount of time between the start of treatment and a worsening of MS that lasts for 3 or 6 months
    - worsening of MS can be measured in 1 or more ways. This includes changes in walking speed, hand control, and EDSS scores

- Number of lesions and active lesions in the brain
- How much the brain changes in size after 6 months of treatment
- How much the amount of a sign of nerve damage in the blood changes at about 2 years compared with the start of the study
- Changes in physical symptoms that people report impacts their daily life
- The number and seriousness of unwanted effects
- How fenebrutinib gets to different parts of the body, and how the body changes and gets rid of it

**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 options of treatment.

**Risks associated with the study drugs** Participants may have unwanted effects of the drugs 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.

Participants will be told about the known unwanted effects of fenebrutinib and teriflunomide and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. The only known unwanted effect of fenebrutinib is a high level of liver markers in the blood.

Known unwanted effects of teriflunomide include pain or discomfort in the head, wanting to throw up, hair thinning or loss, frequent watery stools, and a high level of liver markers in the blood.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

**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.

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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