ForPatients
by Roche

Multiple Sclerosis (MS) Relapsing Multiple Sclerosis (RMS)

A clinical trial to investigate the effectiveness of fenebrutinib compared with placebo in people with relapsing multiple sclerosis.

A Study to Investigate the Efficacy of Fenebrutinib in Relapsing Multiple Sclerosis (RMS)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	6 Countries	NCT05119569 2021-003772-14 GN43271

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

Trial Summary:

This is a study evaluating the effect of fenebrutinib on brain magnetic resonance imaging (MRI) in participants with RMS. The safety and pharmacokinetics of fenebrutinib will also be evaluated. Participants will be randomized to receive either fenebrutinib or placebo.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT05119569 2021-003772-14 GN43271
Trial Identifiers

Eligibility Criteria:

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

Why is the FENopta clinical trial needed?

Relapsing multiple sclerosis (RMS) is a disease that affects the central nervous system, and can worsen over time causing physical and cognitive (i.e. mental) impairment and disability. New drugs which help to prevent disease worsening remain an unmet need. Fenebrutinib is an experimental drug, which means health authorities have not approved fenebrutinib for the treatment of RMS. Researchers hope that using drugs, like fenebrutinib, will provide better health outcomes for people with RMS.

How does the FENopta clinical trial work?

This clinical trial is recruiting people who have a health condition called RMS. People can take part if they have had:

- At least two relapses within the previous two years or one relapse within one year of screening, OR
- At least one new damaged area of the brain (known as a lesion) within the past six months.

The purpose of this clinical trial is to compare the effects, good or bad, of fenebrutinib against placebo in people with RMS. During the double-blind treatment (DBT) phase of the clinical trial, patients who take part in this clinical trial will receive either fenebrutinib or placebo, which means that one of the groups will be given a substance with no active ingredients (also known as a 'placebo'); it looks like the drug being tested. Comparing results from the different groups helps the researchers know whether any changes seen are a result of the drug or occurring by chance. During the DBT phase neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in, if their safety is at risk.

Participants will be given the clinical trial treatment, i.e., fenebrutinib or placebo, for 12 weeks (approximately three months).

Participants will be seen by the clinical trial doctor every four weeks during the DBT phase. These hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. These checks may include:

- Brain magnetic resonance imaging (MRI) scans
- Tests to measure the activity of the heart
- Tests to check how well the brain processes information and how the RMS is progressing (assessing things like balance and how well participants can see and hear)
- Blood and urine sample collection
- Removal of fluid from around the brain and spinal cord using a needle (known as a lumbar puncture). This test is optional for participants; samples will be used to test how certain proteins or genes affect participants' response to the study treatment.

Once the DBT phase of the clinical trial is complete, patients may be given the option to take part in a further open-label extension (OLE) phase of the trial, which means everyone involved, including the participants and the doctors, know which medicine is being used. All patients who take part in the OLE phase will receive fenebrutinib for at least two years, and participants will continue to be seen regularly by the clinical trial doctor.

After stopping treatment (either after the DBT phase or the OLE phase), participants will continue to be seen by the clinical trial doctor for roughly four weeks. Participants' total

time in the DBT phase of the clinical trial will be approximately three months, plus four weeks of follow-up. If participants continue into the OLE phase of the trial, their total time in the clinical trial will be approximately two years. Participants are free to stop trial treatment and leave the clinical trial at any time.

What are the main endpoints of the FENopta clinical trial?

The main clinical trial endpoint (the main results that are measured in the trial to see if the clinical trial treatment has worked) is: how well a participant's RMS responds to fenebrutinib treatment compared with placebo as measured by the total number of new lesions seen on MRI scans of the brain at Weeks 4, 8, and 12.

The other clinical trial endpoints include: the number and seriousness of any side effects experienced by the participant while taking the trial treatment, and blood levels of fenebrutinib .

Who can take part in this clinical trial?

People can take part in this trial if they are aged between 18#55 years old, have been diagnosed with RMS, and have experienced one of the following:

- At least two relapses of their MS within the previous two years, or one relapse within one year of screening, OR
- At least one new brain lesion confirmed by MRI scan within the past six months.

People may not be able to take part in this trial if:

- They have had symptoms of RMS for longer than 10 years
- Are/planning to become pregnant, or are breastfeeding
- Have a history of cancer or certain other medical conditions.

What treatments will participants be given in this clinical trial?

Everyone who joins this clinical trial will be split into one of two groups randomly and given either:

- Fenebrutinib, given as four oral tablets (two tablets, twice a day) every day for 12 weeks

- OR a placebo, given as four oral tablets (two tablets, twice a day) every day for 12 weeks.

Participants will have a 1 in 3 chance (approximately 33% chance) of receiving placebo and a 2 in 3 chance (approximately 67% chance) of receiving fenebrutinib. Neither participants nor the clinical trial doctor can choose or know the group that any participants are in. However, the clinical trial doctor can find out which group a participant is in if their safety is at risk.

Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the FENopta clinical trial

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

Fenebrutinib

Potential participants will be told about the known side effects of fenebrutinib, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

Fenebrutinib placebo will be given as oral tablets (to be swallowed). Participants will be told about any known side effects of oral administration.

Potential benefits associated with the FENopta clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

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