Share the commitment. Shape tomorrow.

Help create a brighter future for people living with PPMS.

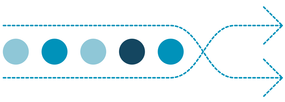
We invite you to consider participation in our innovative FENtrepid Study. Study participants will be part of a team of PPMS patients, clinicians and scientists seeking to determine whether an investigational new drug is a potentially superior treatment option.

The FENtrepid Study seeks to advance treatment for PPMS.

Find a Study Site › | Take the Pre-Screener ›

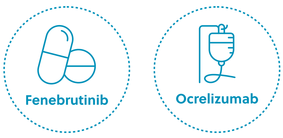
Study Overview

The FENtrepid Study is assessing how safe and effective an investigational study drug is in treating PPMS compared to ocrelizumab. **No participants will receive only a placebo—a "dummy drug" that contains no active medicine.** The study will last for approximately 3 years and 4 months.



Everyone who joins this clinical trial will be split into two groups randomly and receive either the investigational drug (fenebrutinib) or ocrelizumab.

Fenebrutinib will be given as tablets to take by mouth, twice a day, whereas ocrelizumab will be given as a drip into the vein (an intravenous infusion), once every six months.



You will have a 1 in 2 chance of receiving either:

- **Two pills of fenebrutinib twice a day, as well as a "dummy" treatment that is given like an infusion of ocrelizumab every 24 weeks but contains no active ingredients**
- **An infusion of ocrelizumab every 24 weeks, as well as a "dummy" treatment that is given like two pills of fenebrutinib twice a day but contains no active ingredients**

This is a "double-dummy" clinical trial, which means that both groups will be given treatments that look exactly the same 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.

You can leave this clinical trial at any time and you will not lose your access to regular care.

Participation Requirements

During the FENtrepid Study, you will need to visit a study clinic at least 20 times. This is so that we can monitor your general health and see how you are responding to your assigned study drug. On average, these visits will occur once every 3 months, however your first few visits will be more frequent than this.

You may discontinue study treatment at any time and continue to attend study visits. If so, you will stop receiving any study drug.

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Manage Consent Preferences

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Eligibility

We are looking for people dedicated to improving PPMS treatment for all. Please answer the questions below to see if you may be eligible for the FENtrepid Study.

Completing this questionnaire does not obligate you to participate in the study. Your answers will help determine if you may be eligible. If your answers indicate you may be eligible, you will have the opportunity to contact a clinic site near you to learn more about the study.

1. Have you been diagnosed with primary progressive multiple sclerosis?
   - ◯ Yes
   - ◯ No
2. What is your current age?
   - Enter age
3. Are you able to walk?
   - ◯ Yes
   - ◯ No
4. Have you ever been treated with Cytoxan (cyclophosphamide), Lemtrada (alemtuzumab), Mavenclad (cladribine), Novantrone (Mitoxantrone), or Zinbryta (daclizumab)?
   - ◯ Yes
   - ◯ No
   - ◯ Not sure
5. Do any of the following apply to you? (check all that apply)
   - ◯ Pregnant or breastfeeding
   - ◯ Cancer within the last 10 years (except skin cancers or cancer of the cervix)
   - ◯ History of hepatitis B, hepatitis C or HIV
   - ◯ History of a stroke or transient ischemic attack (TIA)
   - ◯ Tumor of the brain or spinal cord
   - ◯ Unable to get an MRI
   - ◯ None of these apply to me

Submit Responses and See if You Qualify ›

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Eligibility

Thank you for your interest.

Your response indicates that you are not eligible for the FENtrepid Study.

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Information about the FENtrepid Study is provided on this website so you can learn about it. This may help you decide whether the study is right for you. It may also be more useful in your discussions with your doctor, family and caregiver. The information is not intended to be promotional. The drug being studied has not been approved by the FDA, EMA or other regulatory agency for the disease being studied.

Eligibility

You may be eligible to take part in the FENtrepid Study!

If you think this clinical trial may be suitable for you and would like to learn more, enter your ZIP code below to find the closest study site.

Enter ZIP code

Find a Study Site ›

This information will remain private.

If you decide you would like to take part, the clinic will carry out some tests to make sure you're eligible for the study.

You may also contact us to learn more about the FENtrepid Study and be connected to a trial site:

Clinical Trial Information

Information and support about Genentech-sponsored trials:

Phone: (888) 662-6728

Hours: Monday–Friday, 5am–5pm PT

Or click here to chat with a representative

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About Clinical Studies

A clinical study (also known as a clinical trial) is a carefully controlled scientific investigation that helps us answer questions about an investigational drug, such as:

- **Is it safe?**
- **Does it work?**
- **Does it work better than another treatment?**

What are the different phases of clinical studies?

There are 4 main phases of clinical studies – with 1 being the earliest and 4 being the latest. The FENtrepid Study is a phase 3 clinical study.

Phase 1

To assess the initial safety of an investigational drug in a small number of participants

(usually 20-80 healthy individuals)

→

Phase 2

To evaluate safety and efficacy by testing it on a larger group of participants

(usually 100-300 individuals)

→

Phase 3

To assess safety and efficacy on an even larger number of participants; often tested against any existing treatments

(usually 1,000-3,000 individuals)

→

Approved for use

→

Phase 4

To collect information about safety and efficacy in a "real-world" setting following a drug's approval for use

An investigational drug generally enters the next phase if it meets the objectives of the previous phase(s). Sometimes, more than one study must be conducted per phase.

Why take part in a clinical study?

There are many reasons why people take part in a clinical study, for example:

- **Regular health monitoring throughout the study**
- **Study-related drugs and procedures provided at no cost**
- **The opportunity to contribute to our scientific understanding of a condition**

What are the risks of taking part in a clinical study?

There may be some risks or discomforts involved in taking part in a clinical study, for example:

- **There are no guarantees that a participant's health will improve**
- **The investigational drug may cause side effects**
- **Some of the procedures may carry their own risks or be uncomfortable**

Participant safety is the top priority of every clinical study. Governments have strict rules to protect the safety and privacy of study participants.

What happens if I decide to take part in a clinical study?

- First, you will be asked to read and sign an informed consent form (ICF) to show that you understand the study and that you agree to being involved. The ICF describes what will happen and when.
- Once this is signed, the study team will carry out some assessments to see if you are eligible.
- If you are eligible, you will be asked to come to a clinic for some health checks. Every study is different, so the number of visits and time between them will differ depending on the study.

Do I have to join?

Taking part in a clinical study is a personal decision and no one has to join if they don't want to. You may also leave a study at any time without any impact on your usual healthcare.

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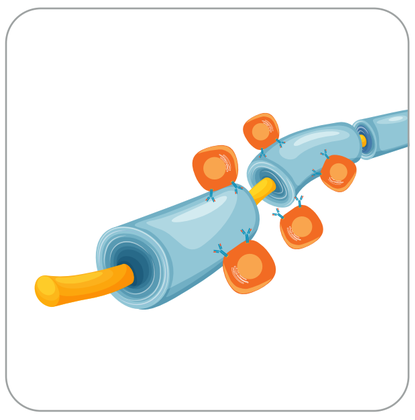
Study Drugs

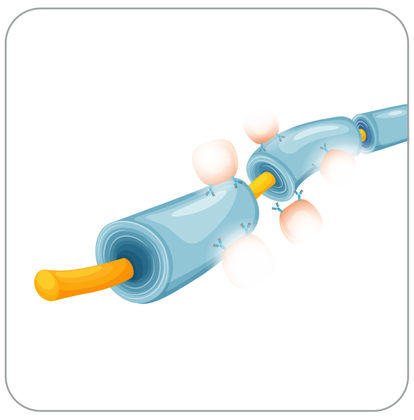
Everyone who joins this clinical trial will be split into two groups randomly and receive either the investigational drug (fenebrutinib) or ocrelizumab.

About the Investigational Drug

The immune system is a complete network of cells that work together to protect the body from harmful substances.

B cells are one component of this network. They produce antibodies to help the body fight harmful substances, but in some autoimmune conditions, such as multiple sclerosis, B cells can overreact and cause harm.





The investigational drug, fenebrutinib, is designed to work by suppressing B cells.

Fenebrutinib has been studied in more than 1,200 people to date across several inflammatory diseases

About Ocrelizumab

Ocrelizumab is an approved therapy for primary progressive MS (PPMS). It is administered via infusion twice per year.

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For more information about the FENtrepid Study, visit:

ForPatients by Roche

clinicaltrials.gov

FENtrepid Study in the news:

MS Trial Alert: Investigators Recruiting for Phase 3 Trial Comparing Experimental Fenebrutinib to Ocrevus® in Primary Progressive MS

Global Phase 3 Trials of Fenebrutinib Enrolling Relapsing and PPMS Patients

#MSVirtual2020 – Roche Launches Phase 3 Clinical Program to Test Fenebrutinib

To learn more about multiple sclerosis and the organizations dedicated to understanding and treating this disease, visit the following websites:

American Autoimmune Related Diseases Association, Inc.

Multiple Sclerosis Association of America

National Multiple Sclerosis Society

Multiple Sclerosis International Federation

US Multiple Sclerosis Foundation

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Study Site Locator

Interested in enrolling? Enter your ZIP code to find a study site near you.

Take the Pre-Screener ›

Enter your ZIP code | Search radius 50 km | Results 10 | Search

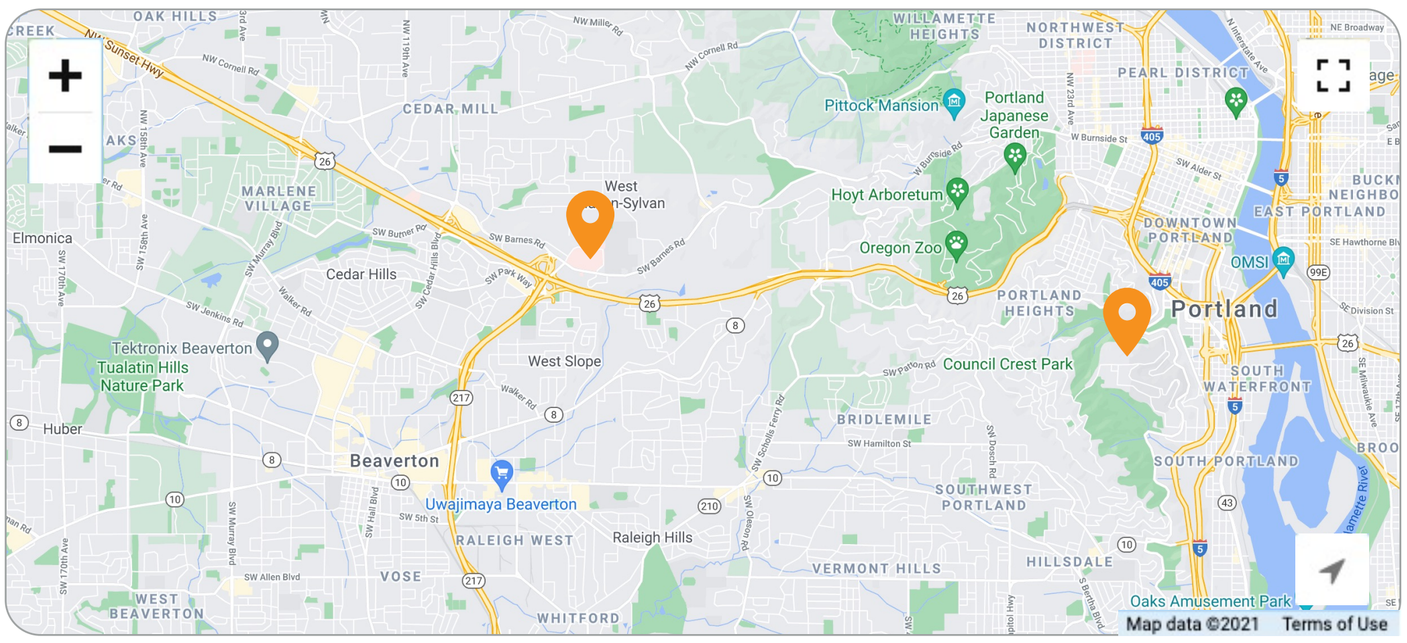
This information will remain private.

Providence Brain and Spine Institute

Portland, OR 97225

Oregon Health and Sciences University

Portland, OR 97239



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