

## Healthy Volunteers

### A study medicine (fenebrutinib) manufactured in different ways – how do different fenebrutinib formulations move through the body

A phase 1, single center, randomized, open-label study investigating the effect of formulation, and active pharmaceutical ingredient particle size on the pharmacokinetics of fenebrutinib in healthy subjects

**Trial Status**  
Completed

**Trial Runs In**  
1 Countries

**Trial Identifier**  
ISRCTN17780768 GP43970

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*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 clinical trial tested a new medicine called “fenebrutinib” to understand how different manufacturing processes affect the behavior of different formulations in the body. The study took place at one study site in the United Kingdom. The trial was designed as a phase 1, randomized, open-label study, meaning that participants were randomly assigned to different treatment groups and both the researchers and participants knew which treatment was being administered.

**Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)**      **Phase 1**  
Sponsor      Phase

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**ISRCTN17780768 GP43970**  
Trial Identifiers

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#### ***Eligibility Criteria:***

**Gender**  
Male and female

**Age**  
18 to 60 years old

**Healthy Volunteers**  
Yes

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**Background and study aims** The sponsor is developing the test medicine fenebrutinib for the potential treatment of multiple sclerosis (MS). MS is a condition that can affect the brain and spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance, and affects about 2.3 million people worldwide. There are medical procedures available that may involve piercing or cutting into the body or inserting instruments (invasive treatments) that target a type of

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white blood cells called B-cells have been shown to be an effective treatment of MS, however, the Sponsor is developing a medicine that can be taken orally (by mouth) which would provide a less invasive therapeutic option for patients with MS. This three-part healthy volunteer trial will try to identify how new recipes (formulations) of the test medicine are taken up by the body (pharmacokinetics), the level of test medicine in the blood following oral dosing (relative bioavailability) and try to provide additional safety and tolerability information for the test medicine.

**Who can participate?** Male and female volunteers of non-childbearing potential, aged between 18 and 60 years.

**What does the study involve?** In Part 1 and Part 2, up to 15 volunteers will receive single oral doses of different recipes of the test medicine across three periods. Part 3 is optional, and if utilized, up to 16 volunteers will receive single doses of different recipes of the test medicine across two periods. In each part, volunteers will be discharged on Day 3 of the final period and will receive a follow-up phone call 7 – 10 days after the final dose. Volunteers' blood will be taken throughout the study for analysis of the test medicine and for their safety. Volunteers are expected to be involved in this study for 7 weeks for Part 1 and Part 2, and 6 weeks for Part 3, from screening to the follow-up call.

**What are the possible benefits and risks of participating?** This is a healthy volunteer study. Participants will be administered fenebrutinib only for research purposes and it is not intended that the participants will receive any benefit from it. However, the information learned in this study may help future patients. Participants will be compensated for taking part in this research study with an inconvenience allowance. It is considered that the risk/benefit evaluation in this study supports the use of healthy volunteers. As MS affects both men and women, both healthy male volunteers and healthy female volunteers of non-childbearing potential will be enrolled in this study. There is always a risk that the stipend in healthy volunteer studies could represent coercion. The time spent in the clinic, travel, inconvenience and other expenses factor in calculating the stipend. Perception of risk is not considered in this calculation. Volunteers may experience side effects from the test medicine. Full information on possible side effects is provided to volunteers in the Participant Information Sheet and Informed Consent Form. When investigating new medicines there is also a risk of unexpected side effects and occasionally allergic reactions. All volunteers will be closely monitored during the study and safety assessments will be performed at regular intervals. Risks are further mitigated by ensuring that only volunteers who meet all inclusion/exclusion criteria are included and that if the safety of any volunteer represents a concern they will be withdrawn. There will be an extended period of fasting for the volunteers taking part in this study. To ensure an adequate fluid intake, the volunteers will be allowed fluids up to 1 hour before dosing and from 1 hour after dosing, will be provided with 240 ml of water at dosing, and will be monitored for signs of dehydration and fatigue. Blood samples will be collected during the study. Collection of these samples can cause soreness and bruising of the arms but these problems usually clear up within a few days to a few weeks. ECG stickers on volunteers'

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chests and limbs may cause some local irritation and may be uncomfortable to remove but volunteers will be closely monitored to ensure any local irritation does not persist.

**Where is the study run from?** Genentech, Inc. c/o F. Hoffmann-La Roche Ltd (Switzerland)

**Who is funding the study?** Genentech, Inc. c/o F. Hoffmann-La Roche Ltd (Switzerland)

**Who is the main contact?** Trial Information Support Line (TISL), [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)