ForPatients
by Roche

Multiple Sclerosis (MS) Metabolic Disorder Impaired hepatic function

A phase I, open-label, single-dose study to evaluate the effect of mild or moderate hepatic impairment on the pharmacokinetics of fenebrutinib

Trial Status	Trial Runs In	Trial Identifier
Recruiting	2 Countries	GP44943

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 effect of various degrees of reduced liver function on the processing of fenebrutinib in the body

Genentech Inc. (Switzerland)
Sponsor

GP44943
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 75 years of age	Yes

Background and study aims:

A disease of the brain and spinal cord (central nervous system) called multiple sclerosis (MS), is a long-lasting (chronic) disease in which the body attacks the protective covering around nerves and damages the nerves. Fenebrutinib is an experimental drug being developed for the treatment of MS. Health authorities have not yet approved fenebrutinib for the treatment of MS.

The main aim of the study is to find out how mild or moderate liver damage (mild or moderate hepatic impairment) will affect the breakdown and removal of the study drug (fenebrutinib) from the body (this is called pharmacokinetics [PK]).

Who can participate?

People between 18 and 75 years of age with normal liver function or with mild or moderate liver damage (mild or moderate hepatic impairment) can participate in this study.

What does the study involve?

Participants will need to be a part of the study for about 5 weeks including the screening period. The study will include the following parts:

- A screening period of up to 28 days to check the eligibility of participants to take part in the study.
- A dosing/treatment period: Participants with normal liver function and mild or moderate liver damage will receive a single dose of fenebrutinib, by mouth (orally) on Day 1. Participants will have to get admitted to the clinic 1 day before receiving the treatment (Day -1) and stay in the clinic until Day 5.
- A follow-up phone call to check on the participant will be made 7 days after the study drug administration to check on their well-being.

What are the possible benefits and risks of participating?

Fenebrutinib is an experimental drug and is being given purely for research purposes, it is not intended that participants will receive any benefit from this study, but the information learned from this study may be useful to treat future patients of multiple sclerosis. Participants may receive monetary compensation for taking part in the study.

Participants may have side effects due to fenebrutinib or procedures used in this study. Side effects can be mild to severe and even life-threatening or fatal, and they can vary from person to person. Full information on risks associated with fenebrutinib is provided to volunteers in the 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. Blood samples will be collected during the study. Collection of these samples can cause pain, bruising, or infection where the needle is inserted. Electrocardiograms (ECGs) will be taken in this study. ECG patches may cause a skin reaction such as redness or itching, or localized skin discomforts and/or hair loss associated with the placement of ECG leads.

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug. Participants who are pregnant, become pregnant or are currently breastfeeding cannot take part in this study.

Where is the study run from?
Genentech Inc. (Switzerland)

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Who is funding the study?
Genentech Inc. (Switzerland)

Who is the main contact?
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