

Multiple Sclerosis (MS)

A phase I, open-label, single-dose study to evaluate the effect of severe renal impairment on the pharmacokinetics of fenebrutinib

Trial Status
Recruiting

Trial Runs In
1 Countries

Trial Identifier
GP44942

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 highly reduced kidney function on the processing of fenebrutinib in the body

Genentech Inc.
Sponsor

GP44942
Trial Identifiers

Eligibility Criteria:

Gender
Both

Age
18 to 75 years of age

Healthy Volunteers
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 severe kidney damage (severe renal impairment) will affect the breakdown and removal of the study drug (fenebrutinib) from the body (this is called pharmacokinetics [PK]).

Who can participate?

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People between 18 to 75 years of age with normal kidney function or severe kidney damage (severe renal impairment) can participate in this study.

What does the study involve?

Participants will be part of this study for approximately 5 weeks. The study will be conducted in 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 during which participants with normal kidney function and severe kidney 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 4.
- 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 not all potential risks are 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 the study.

Where is the study run from?

ForPatients

by Roche

Genentech Inc. (Switzerland)

Who is funding the study?

Genentech Inc. (Switzerland)

Who is the main contact?

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