ForPatients
by Roche

Multiple Sclerosis (MS) Relapsing Multiple Sclerosis (RMS)

Testing different doses of a new medicine (fenebrutinib) and its effect on heart rhythm (QT interval) in healthy people

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	ISRCTN26497758 GP42654

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 was done in healthy people to test a new medicine called, “fenebrutinib,” being developed for the treatment of multiple sclerosis or MS. This study was done to find out if fenebrutinib had any effect on the “QT interval,” a measure of a part of the heart’s electrical signal. Doctors need to know which medicines increase the QT interval so that patients can be monitored for an increased risk for heart-related side effects. This was a randomized, double-blind, placebo-controlled, single ascending dose, Phase 1 study, to test the safety, tolerability, and pharmacokinetics of fenebrutinib in healthy people.

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

Phase 1
Phase

ISRCTN26497758 GP42654
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 60 years	Yes

Background and study aims

Healthy volunteers were enrolled at one study center in the USA to evaluate the safety, tolerability, and pharmacokinetics of fenebrutinib which is being developed for the treatment of multiple sclerosis. Sixteen people joined Part A to look at safety and pharmacokinetics. Eighty-five people joined Part B to look at the effect on QT interval. Results showed fenebrutinib to be safe and tolerable at the doses tested while some non-serious side effects occurred. Fenebrutinib did not increase the QT interval in any significant manner.

ForPatients
by Roche

This is a two-part study of an investigational drug called fenebrutinib that will be performed in healthy volunteers. Part A will evaluate the safety and drug levels in the blood of single doses of fenebrutinib. This information will help with the selection of the doses to test in part B. Part B of the study will primarily evaluate whether fenebrutinib has any effect on the electrocardiogram, a measurement of the heart's electrical activity.

Who can participate?
Healthy volunteers

What does the study involve?
In part A of the study, a single dose of oral fenebrutinib or placebo will be given to volunteers to evaluate the safety and drug levels in the blood. This information will help with the selection of the doses to test in part B. In part B of the study, on different days volunteers will be given a single dose of fenebrutinib (at two different dose levels), moxifloxacin (an antibiotic), and placebo. The objective of part B is to evaluate whether fenebrutinib has any effect on the electrocardiogram, a measurement of the heart's electrical activity. Part B will also evaluate the safety and blood levels of fenebrutinib. Volunteers will participate in either part A or B, but not both.

What are the possible benefits and risks of participating?
Study volunteers will not receive any medical benefit. They will be compensated for their time.
One identified risk of fenebrutinib is potential increased blood level of liver enzymes. Other risks that have not been observed but are theoretically possible include infection, change in levels of certain cells in the blood, liver injury, effect on vaccinations, bleeding, nausea, vomiting, diarrhea, abnormal heart rhythm, inflammation (swelling or redness) of blood vessels, ability to fight cancer, birth defects, or rash.

Where is the study run from?
Genentech (USA)

Who is funding the study?
F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com, reference Protocol ID GP42654