ForPatients
by Roche

Healthy Volunteers

A study to find out if people get the same amount of medicine when they take the two different forms.

A Study to Investigate the Bioequivalence of Two Different Forms of Entrectinib (Forms A and C) Under Fasted Conditions in Healthy Subjects

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03796013 GP41049

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Randomized, Open-Label, Two-Treatment, Two-Period, Two-Way Crossover Study to Investigate the Bioequivalence of Entrectinib Polymorph Forms A and C Under Fasted Conditions in Healthy Subjects

Trial Summary:

This study aims to demonstrate similarities between two different forms of entrectinib (A and C) when administered under fasted conditions in healthy subjects.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03796013 GP41049
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 60 Years	Accepts Healthy Volunteers

Entrectinib is a medicine for treating different kinds of cancer. In this study, healthy people took two different forms of entrectinib – Form A and Form C. Researchers wanted to find out if people get the same amount of medicine when they take either form of the medicine – Form A or Form C.

Inclusion Criteria:

- Healthy in the opinion of the investigator. Healthy is defined by the absence of evidence of any active disease or clinically significant medical condition based on a detailed medical history and examination
- Negative test results for Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus (HIV)
- Females must not be pregnant or breastfeeding, and females of childbearing potential will agree to use highly-effective contraception. Females of childbearing potential must also agree to refrain from donating eggs during the treatment period and for 6 weeks after the final dose of study drug
- Males must agree to use contraception and to refrain from sperm donation from check-in (Day -1 of Period 1) to 90 days after the final dose of study drug

Exclusion Criteria:

- History of gastrointestinal surgery or other gastrointestinal disorder that might affect absorption of medicines from the gastrointestinal tract
- Presence of a clinically significant disease, illness, medical condition or disorder, or any other medical history determined by the investigator to be clinically significant and relevant. Ongoing chronic disorders which are not considered clinically significant are permissible providing they are stable
- Clinically significant change in health status, as judged by the investigator, or any major illness within the 4 weeks before screening, or clinically significant acute infection or febrile illness within the 14 days before screening
- Participation in any other clinical study involving an investigational medicinal product (IMP) or device within 30 days or 5 half-lives (if known), whichever is longer, before screening