ForPatients
by Roche

Hepatic Insufficiency

A Study to Investigate the Effect of Impaired Hepatic Function on the Pharmacokinetics of Entrectinib in Volunteers With Different Levels of Hepatic Function

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT04226833 2019-003065-17 GP41174

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:

An Open-Label, One Treatment, Four Group, Parallel Group Study to Investigate the Effect of Impaired Hepatic Function on the Pharmacokinetics of Entrectinib in Volunteers With Different Levels of Hepatic Function

Trial Summary:

This clinical trial was done to study an approved medicine called, “entrectinib”, for the treatment of patients with certain types of cancers. This study was done to find out what happens to entrectinib in the body when it is given to people who have an unhealthy liver. Researchers also wanted to know if there was a relationship between the amount of entrectinib available in the body and the health status and function of the liver. Thirty-eight people took part in this study at three study centers in three countries. Some people had a healthy liver while others had an unhealthy liver.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT04226833 2019-003065-17 GP41174
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	Accepts Healthy Volunteers

Inclusion Criteria:

All participants:

- A body mass index (BMI) between 18.0 and 38.0 kg/m2, and weighing at least 50 kg
- Agreement to comply with measures to prevent pregnancy and restrictions on sperm donation.

Participants with normal hepatic function:

- Normal hepatic function and no history of clinically significant hepatic dysfunction.
- Healthy for age-group in the opinion of the Investigator.

Participants with hepatic impairment:

- Mild, moderate or severe hepatic dysfunction (i.e. Child-Pugh A, B or C, NCIODWG Mild, Moderate or Severe) arising from cirrhosis of the liver as the result of parenchymal liver disease.
- Stable hepatic function.

Exclusion Criteria:

- Transjugular intrahepatic portosystemic shunt or other porta-caval shunt.
- A history of gastrointestinal hemorrhage due to esophageal varices or peptic ulcers.
- Recent history or signs of severe hepatic encephalopathy (e.g., a portal systemic encephalopathy score >2).
- Advanced ascites or ascites which require emptying and albumin supplementation.
- Hepatocellular carcinoma, acute liver disease or serum ALT or AST not consistent with stable disease.
- Recipient of a liver transplant.
- Uncontrolled hypertension.
- Clinically significant impairment of renal function.
- A history of gastrointestinal surgery or other gastrointestinal disorder that might affect absorption of medicines from the gastrointestinal tract.
- Clinically significant change in health status, or any major illness, or clinically significant acute infection or febrile illness.
- Women who are pregnant or lactating.
- Presence of any abnormal ECG finding, which is clinically significant.
- Use of moderate or potent inhibitors or inducers of cytochrome P450 3A4 enzyme.
- Participation in any other clinical study involving administration of an investigational medicinal product or use of an unapproved device.
- A positive test result for human immunodeficiency virus (HIV).
- Known history of clinically significant hypersensitivity, or severe allergic reaction, to entrectinib or related compounds or other excipients in the entrectinib formulation.