

What happens to a medicine (pralsetinib) when given to people with unhealthy livers

A Phase I, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics and Safety of Pralsetinib in Subjects With Moderate or Severe Hepatic Impairment Compared to Healthy Subjects

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
GP43163

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 phase 1, open-label, single-dose study to evaluate the pharmacokinetics and safety of pralsetinib in subjects with moderate or severe hepatic impairment compared to healthy subjects

Trial Summary:

This clinical trial was done to study a medicine called, “pralsetinib,” that has been approved for certain types of cancers. Researchers wanted to find out how liver function affected the amount of medicine in the body. Men and women took part in this study if they had healthy liver function (Group 1); moderate liver disease (Group 2); or severe liver disease (Group 3). Researchers measured and compared pralsetinib in blood samples collected from the three groups of people. This was an open-label, single-dose study.

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

Sponsor

Phase 1

Phase

GP43163

Trial Identifiers

Eligibility Criteria:

Gender

Male and Female

Age

18 to 74 years

Healthy Volunteers

Yes

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Twenty-nine men and women were enrolled at four study sites in the USA to find out how pralsetinib behaved in the body. The main finding was a comparison of pralsetinib levels in groups of people with healthy liver function versus those with liver disease. Information from this study may be used to guide other studies with more people or to help doctors give the medicine safely to people with liver disease.

Who can participate? Subjects aged between 18 to 74 years who are healthy, or have liver impairment.

What does the study involve? (what interventions will be compared, will all participants receive the same treatment, what measurements will be taken)

During this study, participants have two visits, including a screening visit up to 34 days before the start of the study, and a stay in the study site lasting 10 days and 9 nights. The total duration of participation in the study will be about 10 days. In this study, the study doctor, and the sponsor will know the drugs and the doses that are given. Participants will be given a single oral (by mouth) dose of 200 mg pralsetinib given as 2 capsules on Day 1 given in the morning with one cup of water after an overnight fast (no food or drink other than water) of at least 8 hours. Then, it will be required to remain fasting for at least 2 hours after dosing (a total fast of at least 10 hours). One will not be allowed to drink water (except for the water given with dosing) from 1 hour before dosing to 2 hours after taking the capsules.

This study requires that a blood sample be obtained that may be used for additional research involving genetic analysis of blood. If participants do not wish to have this sample collected, will not be permitted to participate in this study. There is an additional research that may involve long-term storage for future analysis of blood for the Research Biosample Repository (RBR). Participants will be asked to sign a separate section of the informed consent for this additional research. If participants do not wish to participate in this additional research, the participation in this main research study will not be affected.

What are the possible benefits and risks of participating? Participation in this study is purely for research purposes, and will not improve one's health or treat any medical problems. One may benefit by having physical examinations. The results of laboratory tests done at the screening visit will be made available upon request. However, if disqualified for study participation by other screening procedures, some laboratory tests may not be conducted.

Participants may have side effects from the drugs 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. Talk to the study doctor right away if one experiences any side effects during the study. There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing

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an unborn child to study drug, as described in Section 1.6. If participants are pregnant, become pregnant, or are currently breastfeeding, one cannot take part in this study.

Where is the study run from? United States

When is the study starting and how long is it expected to run for? November 2021 to June 2022

Who is funding the study? Genentech, Inc

Who is the main contact? global-roche-genentech-trials@gene.com