ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A study to measure how much of the study drug GDC-6036 is absorbed and the effect of food on absorption in healthy participants

A Phase 1, Open-Label, Single-Dose, Randomized, Three-Period Crossover Study to Evaluate the Relative Bioavailability and Food Effect of GDC-6036 in Healthy Subjects

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	GP43039

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, Randomized, Three-Period Crossover Study to Evaluate the Relative Bioavailability and Food Effect of GDC-6036 in Healthy Subjects

Trial Summary:

GDC-6036 is an experimental drug (not yet approved by health authorities) being developed for the treatment of non-small cell lung cancer (NSCLC), colorectal cancer, and other tumor types. The aims of this study are:

- To compare how much of the study drug is absorbed and how long it takes to get eliminated in two different forms of GDC-6036 (tablet and capsule)
- To evaluate the effect food has on the absorption of the study drug in tablet form
- To collect information on any side effects that may occur when the study drug is taken with food and/or without food

GP43039
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male and female	18 to 60 years	Yes

Who can participate?
Healthy male and female volunteers aged 18 to 60 years, inclusive

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What does the study involve?
Participants will be given a single oral dose of GDC-6036 on Day 1 in each period. Within each period, they will receive GDC-6036 as either a capsule after fasting, as a tablet after fasting, or as a tablet after eating a high-fat breakfast, with about one cup of water. Participants will receive each dose regimen once. The order in which participants will receive the different dosing regimens will be determined randomly. There will be a washout period (a time in which no dosing is given) of 5 days between each dosing.

The study drug will be 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. In one of the dosing periods, participants will be required to eat a high-fat breakfast consisting of two eggs fried in butter, two strips of bacon, two slices of toast with butter, 4 ounces of hash brown potatoes, and a cup of whole milk. Participants will need to eat the entire breakfast within 25 minutes, and dosing will be given within 10 minutes after finishing the meal. Participants will be required to remain fasting for 4 hours after dosing (a total fast of 12 hours for the 2 periods without breakfast) and will not be allowed to drink water (except for the water given with dosing) from 1 hour before dosing to 2 hours after dosing.

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct benefits from the study, but the information that is learned may help other people in the future. During the study, some side effects (unwanted effects or health problems) from the study drug or from the study procedures may be experienced. Some of the common side effects are diarrhea, nausea, vomiting, elevated liver enzymes in the blood, fatigue (feeling tired), constipation, headache, abdominal pain, anemia (decrease in red blood cells), cough, decreased appetite, and reduced potassium level in the blood. There may also be a risk in exposing an unborn child to the study drug - the risks for this are not yet known. There may also be unknown, infrequent, and unforeseeable risks associated with the use of the study drug including severe or life-threatening allergic reactions or unexpected interactions with another medication.

Where is the study run from?
Genentech, Inc (USA)

When is the study starting and how long is it expected to run for?
January 2021 to October 2021

Who is funding the study?
Genentech, Inc (USA)

Who is the main contact?
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