

Non-Small Cell Lung Cancer (NSCLC)

A study to find out if taking different forms of a medicine (GDC-6036) results in the same amount of medicine in your body – and the effect of food on the medicine

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
Completed

Trial Runs In
1 Country

Trial Identifier
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 effects of GDC-6036 in healthy subjects

Trial Summary:

This clinical trial was done to study “GDC-6036”, a medicine for the treatment of patients with cancer. This phase 1 study investigated how much medicine was delivered to the body by the capsule and tablet forms – the relative bioavailability of GDC-6036. It also investigated whether there was a difference if GDC-6036 was taken after eating or on an empty stomach – the food effect on GDC-6036. Seventeen healthy men took part in this study at one study center in one country – the USA.

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

Phase 1
Phase

GP43039
Trial Identifiers

Eligibility Criteria:

Gender
Male and female

Age
18 to 60 years old

Healthy Volunteers
Yes

ForPatients

by Roche

Healthy volunteers were enrolled at one study site in USA to evaluate the relative bioavailability of tablet and capsule formulations, and the effect of food, on GDC-6036. Seventeen participants enrolled in the phase 1, open-label, randomized, three-period crossover, single-dose study. Results showed the capsule and tablet formulations to have similar bioavailability. Taking GDC-6036 after a meal slowed down the absorption rate and lowered the peak concentration reached – in comparison to taking GDC-6036 on an empty stomach. Study results will support other ongoing studies on GDC-6036, a *KRAS* G12C inhibitor.