

ForPatients

by Roche

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 Countries

Trial Identifier
GP43039

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

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

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

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empty stomach. Study results will support other ongoing studies on GDC-6036, a *KRAS* G12C inhibitor.