

Inflammatory Bowel Disease (IBD)

A study to find out how safe is it to give people a new medicine called “GDC-8264” – including the effect of food on GDC-8264, and the effect of combining GDC-8264 with other medicines

Trial Status
Completed

Trial Runs In

Trial Identifier
GP41678

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 I, randomized, double-blinded, placebo-controlled study to evaluate the safety, tolerability, and pharmacokinetics of single- and multiple-ascending doses of oral GDC-8264 and the effect of food on the pharmacokinetics of GDC-8264 in healthy volunteers

Trial Summary:

This clinical trial was done to study a new medicine called, “GDC-8264”, for the treatment of patients with “inflammatory bowel disease” or “IBD”. This study was done to find out how safe was it for healthy people to get GDC-8264, and how well GDC-8264 was tolerated. Investigators also wanted to find out the effect of food on GDC-8264, and the effect of GDC-8264 on other medicines (drug-drug interaction). Sixty-eight healthy people took part in this study at one study center in one country.

**F. Hoffmann-La Roche Ltd (Switzerland),
Genentech Inc (USA)**
Sponsor

Phase 1
Phase

GP41678
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
18 to 55 years

Healthy Volunteers
Yes

Healthy volunteers for single ascending dose (SAD; $n=38$), multiple ascending dose (MAD; $n=15$), and drug-drug interaction (DDI; $n=15$) cohorts were enrolled at one study site in

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the Netherlands to evaluate the safety and tolerability of GDC-8264, with potential activity in patients with inflammatory bowel disease (IBD). All 68 healthy volunteers completed the study and comprised the safety-evaluable population. Results showed single and multiple doses of GDC-8264 taken by mouth were safe and well-tolerated. GDC-8264 can be taken with or without food. One type of measurement indicated DDI, while other measurements did not. There were no deaths or serious adverse events. No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.