ForPatients
by Roche

Healthy Volunteers

A study to find out if people get the same amount of medicine (alectinib) - when they take different forms of the medicine - with or without food.

A randomized, open-label, two-treatment, two-part, study to explore the performance of alectinib extemporaneous suspension on alectinib capsule bioavailability in healthy subjects in fed and fasted conditions.

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	GP42776

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

Healthy volunteers for Group 1 (*n*=14) and Group 2 (*n*=7 high fat meals; *n*=7 low fat meals) were enrolled at one study site in the United Kingdom to explore the relative bioavailability of alectinib from oral suspension and hard capsule formulation in healthy subjects under fasted (Group 1) and fed (Group 2) conditions. All 28 participants completed the study. Results showed an increase in alectinib systemic exposure for oral suspension compared to capsule, that was higher in the fed state than in the fasted state. Adverse events (AEs) regardless of attribution occurred in 11 subjects. Three subjects experience related AEs. There were no deaths or serious AEs, and no discontinuations or modifications of the study treatment.

Genentech, Inc.
Sponsor

GP42776
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 60 years	Yes

This clinical trial was done to study a medicine called, “alectinib”, for the treatment of patients with cancer. This study investigated how much medicine was available in the body (relative bioavailability) in different formulations - when alectinib was taken as an oral

suspension and as hard capsules - taken without food (Group 1) and with food (Group 2). Twenty-eight healthy people took part in this study in one country.