

Breast Cancer HER-2 Positive

A study to find out what happens to a new medicine (inavolisib) inside the human body

Trial Status
Completed

Trial Runs In
1 Country

Trial Identifier
GP42652

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-center, study to investigate the absorption, metabolism, excretion, and absolute bioavailability of a single oral dose of [¹⁴C]-labeled inavolisib and IV tracer dose of [¹³C#]-labeled inavolisib in a single cohort of healthy volunteers

Trial Summary:

This clinical trial was done to study a new medicine called, “inavolisib”, for the treatment of patients with cancer. The main questions that researchers wanted to answer included 1) how much inavolisib was removed from the body and through which route was it removed from the body; 2) how much inavolisib was available in the blood when taken as a 9 mg capsule. Eight healthy people took part in this study at one study center in one country.

Genentech, Inc. (USA)
Sponsor

Phase 1
Phase

GP42652
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
18 to 65 years

Healthy Volunteers
Yes

Eight healthy volunteers were enrolled at one study site in USA to evaluate the bioavailability, metabolism, and excretion of inavolisib, a small molecule inhibitor of the Class I PI3K# isoform and with increased potency in PI3K with mutated p110#. All 8 participants completed the study. Results showed inavolisib was removed from the body through passing urine and feces, and the bioavailability of the oral capsule was 76%.

ForPatients

by Roche

There were no deaths or serious AEs. The data from this study will help support further development of inavolisib.