

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 Countries

**Trial Identifier**  
GP42652

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

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