ForPatients
by Roche

Healthy Volunteers

A study to find out what happens to a new medicine inside women's bodies – and to look at different forms of the medicine (giredestrant)

Study to Investigate the Absorption, Metabolism, and Excretion of [14C]-GDC-9545 Following a Single Oral Dose (Part 1) and to Evaluate the Absolute and Relative Bioavailability of Oral Capsule Formulations of GDC-9545 (Part 2) in Healthy Female Subjects of Non-Childbearing Potential

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT04680273 2020-004650-29 GP42662

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 is an open-label, single-center, two part study in healthy female subjects of non-childbearing potential to investigate the absorption, metabolism, and excretion of [14C]-GDC-9545 (Part 1), the absolute bioavailability of formulations F12 and F18 (i.e., GDC-9545/F12 capsule, 30 mg and GDC-9545/F18 capsule, 30 mg) and relative bioavailability of GDC-9545 oral capsule F18 to the F12 formulation (Part 2). It is planned that Part 1 will begin prior to Part 2 of the study, and that the two parts of the study will partially overlap.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT04680273 2020-004650-29 GP42662
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	>=30 Years & <= 65 Years	Accepts Healthy Volunteers

This clinical trial was done to study a new medicine called, "giredestrant", for the treatment of patients with ER+ breast cancer. This study was done to take a detailed look at what happens to giredestrant in the body of healthy women who were not pregnant, unable to have children, and were not breastfeeding. Sixteen healthy women took part in this study at one study center in one country – The United Kingdom.

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