ForPatients
by Roche

Healthy Volunteers

A study to find out if taking different forms of GDC-0134 gives you the same amount of medicine in your body

A Study to Determine the Bioavailability of Various Formulations of GDC-0134 in Healthy Female Participants of Non-Childbearing Potential

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03807739 GP40957

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 Study to Determine the Relative Bioavailability of Various Formulations of GDC-0134 in Healthy Female Subjects of Non-Childbearing Potential

Trial Summary:

This is a two-part study to determine the relative bioavailability of two different prototype capsules of GDC-0134 to that of an existing reference capsule of GDC-0134 under both fed and fasted conditions. The study is open to healthy female participants of non-childbearing potential.

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

NCT03807739 GP40957
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years & # 65 Years	Accepts Healthy Volunteers

This clinical trial was done to study a new medicine called, “GDC-0134”, for the treatment of patients with “amyotrophic lateral sclerosis” – also known as “ALS” and “Lou Gehrig’s disease”. This study was done to find out whether taking three different forms (different formulations) of GDC-0134 gave you the same amount of medicine in your body. The effect of taking the medicine with and without food was also studied. The impact of the

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medicine on patients with ALS was not studied. Twenty-nine healthy people participated in this study at two study centers in USA.

Inclusion Criteria:

- Body mass index (BMI) range 18.5 to 35 kilograms per square meter (kg/m2)
- In good health, determined by no clinically significant findings from medical history, physical examination, 12-lead ECG, and vital signs;
- Clinical laboratory evaluations within the reference range for the test laboratory, unless deemed not clinically significant by the principal investigators (PIs)
- Females of non-childbearing potential only

Exclusion Criteria:

- History or clinical manifestation of any significant medical condition as determined by the PI (or designee)
- History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the PI (or designee)
- History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs
- Use of any prescription medications/products within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration, unless deemed acceptable by the PI
- Use of oral antibiotics within 4 weeks or intravenous antibiotics within 8 weeks prior to the Screening evaluation and during the entire study duration
- Use of any over-the-counter, non-prescription preparations within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration, unless deemed acceptable by the PI
- Use of acid reducing medications (proton pump inhibitors [PPIs], histamine H2-receptor antagonists [H2RAs]) within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration. As an alternative, antacids may be allowed at least 4 hours before or after dose
- Use of any vaccines (including seasonal flu and H1N1 vaccines) within 14 days prior to Check-in (Day -1) for their first treatment period
- Use of tobacco- or nicotine-containing products within 6 months prior to Check-in (Day -1) for their first treatment period and during the entire study
- Any acute or chronic condition or any other reason that, in the opinion of the PI, would limit the subject's ability to complete and/or participate in this clinical study

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