ForPatients
by Roche

Crohn's DiseaseUlcerative ColitisHealthy Volunteers

A study to look at a new medicine called “UTTR1147A” - how safe are different doses for healthy people and patients to take – and how is this medicine processed through the body

A Safety Study of Intravenously Administered UTTR1147A in Healthy Volunteers (HVs), Participants With Ulcerative Colitis (UC), and Participants With Crohn's Disease (CD)

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT02749630 2015-002512-32 GA29469

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:

An Observer-Blinded, Placebo-Controlled, Multiple-Ascending, Dose-Escalation Study to Explore the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Repeat Intravenous Administrations of UTTR1147A in Healthy Volunteers and Patients With Ulcerative Colitis and Crohn's Disease

Trial Summary:

This is a randomized, observer-blinded, placebo-controlled study to evaluate safety, tolerability, immunogenicity, and pharmacokinetics of repeat dosing of intravenous (IV) UTTR1147A. The study will consist of a repeat dose escalation in HVs, in participants with UC, and in participants with CD across multiple sites.

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

NCT02749630 2015-002512-32 GA29469
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 80 Years	Accepts Healthy Volunteers

This clinical trial was done to study a new medicine called, “UTTR1147A”, for the treatment of patients with “ulcerative colitis” and “Crohn’s disease”. This study was done to find out if UTTR1147A was safe for people and what happened to UTTR1147A inside the

body. Sixty-nine people, including 38 healthy people and 31 patients took part in this study at 2 study centers in 2 countries.

Inclusion Criteria:

General inclusion criteria:

- No history of malignancy
- Documentation of age-appropriate cancer screening based on local/country-specific guidelines
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods
- For men: agreement to remain abstinent or use contraceptive measures and agreement to refrain from donating sperm

For HVs Only:

- Age 18 - 50
- Body mass index (BMI) between 18 and 32 kilograms per square meter (kg/m2), inclusive
- In good health, determined by no clinically significant findings from medical history, 12-lead electrocardiogram (ECG), and vital signs, and clinical laboratory evaluations should be within the reference range for the test laboratory unless deemed not clinically significant by the investigator and Sponsor

For Participants with UC or CD:

- Age 18 - 80
- Eligible to receive biologic therapy
- Disease duration of >/= 12 weeks
- Diagnosis of moderate to severe UC or CD

Exclusion Criteria:

General exclusion criteria:

- History of inflammatory skin disorders
- History of any cancer
- History of anaphylaxis, hypersensitivity, or drug allergies
- History of alcoholism or drug addiction
- Positive tests indicating infection for hepatitis C, hepatitis B, or HIV
- Use of a non-biologic investigational drug or participation in an investigational study with a non-biologic drug within 30 days or 5 half-lives of investigational product, whichever is greater, prior to study drug administration
- Use of a biologic investigational therapy or participation in an investigational study involving biologic therapy within 90 days or 5 half-lives, whichever is greater, prior to study drug administration
- History or presence of an abnormal ECG that is clinically significant in the investigator's opinion
- Family history of sudden unexplained death or long QT syndrome
- Any acute or chronic condition that would limit the subject's ability to complete and/or participate in this clinical study
- Pregnant or lactating, or intending to become pregnant for duration of study

For HVs Only:

- Known family history of gastrointestinal (GI) and/or colon cancer
- Prior exposure to UTTR1147A

For Participants with UC or CD:

- Significant uncontrolled co-morbidity, such as neurological, cardiac, pulmonary, renal, hepatic, endocrine, or GI disorders
- History of primary sclerosing cholangitis
- Active anti-TNF induced psoriasiform or eczematous lesions
- Moderate to severe anemia
- Presence of an ileostomy or colostomy
- Total proctocolectomy
- Positive screening for latent mycobacterial tuberculosis infection
- Impaired renal function
- Impared hepatic function