ForPatients
by Roche

Infectious Diseases

A study to compare different doses of fenebrutinib with a “placebo” – in patients with an autoimmune disease called “chronic spontaneous urticaria”

Efficacy and Safety of GDC-0853 in Participants With Refractory Chronic Spontaneous Urticaria (CSU)

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03137069 2016-004624-35 GS39684

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

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety and pharmacokinetics of GDC-0853 compared with placebo in participants with Refractory Chronic Spontaneous Urticaria (CSU) already treated with anti-histamines. Participants have the option to enter the Open-Label Extension (OLE) study after completing the 8-week treatment period.

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT03137069 2016-004624-35 GS39684
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 75 Years	No

Fenebrutinib is a study medicine intended for the treatment of patients with “autoimmune diseases”. Researchers wanted to find out if fenebrutinib was effective in patients with chronic spontaneous urticaria (CSU) – an autoimmune disease. This was a double-blind study where patients and researchers did not know which treatment group each patient belonged to. Some patients got fenebrutinib and others got a placebo (no medicine). This way, the effect of fenebrutinib could be compared against the placebo (no medicine).