

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**  
Completed

**Trial Runs In**  
3 Countries

**Trial Identifier**  
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**  
All

**Age**  
>= 18 Years & <= 75 Years

**Healthy Volunteers**  
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).