

Chronic Spontaneous Urticaria Clinical Trial

A PHASE 3 STUDY OF EFFICACY AND SAFETY OF REMIBRUTINIB IN THE TREATMENT OF CSU IN ADULTS INADEQUATELY CONTROLLED BY H1 ANTIHISTAMINES (REMIX-1)

Sponsor: Novartis

Trial Link: <https://clinicaltrials.gov/ct2/show/NCT05030311>

Medication: Remibrutinib or placebo (randomised 2:1)

Dosing: To be taken orally twice daily for 52 weeks.

Participants in the placebo arm will be switched to active treatment at week 24

Age: ≥ 18

Gender: All

Compensation: \$60 per visit

Duration: 1 year. There will be monthly visits in total for the entire duration of the trial.

About Remibrutinib: Remibrutinib binds and inhibits Bruton's Tyrosine Kinase (BTK) with high selectivity. BTK inhibition targets the immune response thought to be involved in the activation of urticaria.

INCLUSIONS	EXCLUSIONS
<ul style="list-style-type: none"><input type="checkbox"/> CSU inadequately controlled by second generation H1-antihistamines<input type="checkbox"/> Presence of daily itch and hives for ≥ 6 consecutive weeks prior despite the daily use of second generation H1-antihistamines<input type="checkbox"/> Documentation of CSU duration for ≥ 6 months<input type="checkbox"/> Documentation of hives within 3 months	<ul style="list-style-type: none"><input type="checkbox"/> Clearly defined predominant or sole trigger of their chronic urticaria<input type="checkbox"/> Other diseases with symptoms of urticaria<input type="checkbox"/> Any other skin disease associated with chronic itching<input type="checkbox"/> Cardiovascular, neurological, psychiatric, pulmonary, renal, hepatic, endocrine, metabolic, haematological disorders, gastrointestinal disease or immunodeficiency<input type="checkbox"/> Uncontrolled disease states, eg. anaphylaxis, asthma or inflammatory bowel disease<input type="checkbox"/> History or current hepatic disease<input type="checkbox"/> Malignancy of any organ system within the past 5 years<input type="checkbox"/> Known history or evidence of ongoing alcohol or drug abuse within the last 6 months