

Trial of JYB1904 in Chronic Spontaneous Urticaria.

NCT06509334

Status	RECRUITING
Phase	Phase 2
Sponsor	Jemincare
Enrollment	135 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female adult subjects (≥18 years of age).
- Diagnosis of Chronic Spontaneous Urticaria(CSU) ≥3 months prior to Screening Visit 1 and previously inadequately controlled with a second-generation H1 antihistamine.
- Itching and hives lasting ≥6 weeks prior to Screening Visit 1.
- Have a UAS7 (range 0 - 42) ≥16, an ISS7 (range 0 - 21) ≥6, and an HSS7 (range 0 - 21) ≥6 within 7 days prior to randomization.

Exclusion (5)

- Induced urticaria with a defined trigger, including artificial urticaria (cutaneous scratches), cold-contact, heat-contact, solar, pressure, delayed-pressure, water-source, cholinergic, or contact urticaria
- Any other dermatological condition with chronic itching, such as atopic dermatitis, herpetic pemphigoid, herpetic dermatitis, senile itching, or psoriasis, which in the opinion of the investigator may affect the study assessment and study results
- Other conditions with symptoms of urticaria or angioedema, including but not limited to urticarial vasculitis, pigmented urticaria, erythema multiforme, mastocytosis, hereditary urticaria, or acquired/drug-induced urticaria.
- Previous allergic reaction or poor efficacy with omalizumab.
- Contraindication or hypersensitivity to antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, levocetirizine, rupatadine, bilastine) or any of the ingredients.

Locations (1 total)

Peking University People's Hospital, Beijing, Beijing Municipality, China