

A Study to Investigate Efficacy, Safety and Tolerability of Barzolvolimab Versus Placebo in Adults With Cold Induced Urticaria and Symptomatic Dermographism Inadequately Controlled by H1-antihistamines (EMBARQ - ColdU and SD)

NCT07266402

Status	RECRUITING
Phase	Phase 3
Sponsor	Celldex Therapeutics
Enrollment	240 participants

Key Eligibility Criteria

Inclusion (12)

- Males and females, \geq 18 years of age.
 - Diagnosis of cold induced urticaria or symptomatic dermographism \geq 3 months.
 - Diagnosis of cold induced urticaria or symptomatic dermographism despite the use of a stable regimen of second generation non-sedating H1-antihistamine as defined by:
 - The presence of hives for \geq 6 weeks at any time prior to Visit 1 despite the use of H1-antihistamines.
 - Must be on a stable regimen of second generation non-sedating H1-antihistamine for \geq 4 weeks prior to study treatment.
- ... and 7 more (see full listing online)

Exclusion (9)

- Women who are pregnant or nursing.
 - Clearly defined cause for chronic urticaria.
 - Active, pruritic skin condition in addition to cold induced urticaria or symptomatic dermographism.
 - Medical condition that would cause additional risk or interfere with study procedures.
 - Known HIV, hepatitis B or hepatitis C infection.
- ... and 4 more (see full listing online)

Locations (72 total)

Cahaba Dermatology & Skin Health Center, LLC, Birmingham, Alabama, United States
One of a Kind Clinical Research Center, LLC, Scottsdale, Arizona, United States
Kern Research, Inc., Bakersfield, California, United States
... and 69 more locations