

Effects of Inhaled Epinephrine on Systemic Allergic Reactions During Allergy Testing, Immunotherapy or Oral Challenges

NCT07038746

Status	RECRUITING
Phase	Phase 1
Sponsor	Dr. George Luciuk
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (3)

- Males or females, aged \geq 12 years with known or suspected allergen sensitivity who can also have a clinical history of immunoglobulin E (IgE)-mediated allergy, including a documented sensitivity to allergens (i.e., positive skin prick test, or positive in vitro serum IgE).
- Have undergone either a) allergy testing for suspected sensitivity/allergy, b) future oral challenge (food and/or drug) or future OIT to treat existing allergies or c) SCIT AND experienced a SAR Grade 2 or higher, following allergy testing, SCIT, or oral challenges (food and/or drug) for future OIT, and deemed eligible for enrollment by the Principal Investigator.
- For females of child-bearing potential, not pregnant or lactating, willing to use an acceptable contraception* method between Screening and End-of-Study Visits.

Exclusion (7)

- Known reaction or sensitivity to epinephrine or any of the ingredients of inhaled epinephrine.
 - Known history or presence of clinically disease/condition that could confound the results of the study or place the subject at undue or additional risk per the judgment of the Investigator.
 - Abnormal vital signs at screening (i.e., systolic blood pressure: $<$ 90 or $>$ 140 mmHg, diastolic blood pressure: $<$ 40 or $>$ 90 mmHg or, heart rate: $<$ 45 or $>$ 100 bpm), respiration rate $<$ 8 or $>$ 20 resp./min.
 - Females who are pregnant, plan to become pregnant or lactating.
 - Participation in another clinical study involving an investigational drug within 30 days prior to screening, an investigational biologic within 60 days prior to screening, or current/planned participation in another interventional study during this study.
- ... and 2 more (see full listing online)

Locations (1 total)

Kokua Pharma Inc., Richmond, British Columbia, Canada