# Clinical Trials Data ALK - Document 18

# MK-8237 (SCH900237) Biomarker Study in Participants With Allergic Rhinitis or Rhinoconjunctivitis (MK-8237-009)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01852825

"eligibilityCriteria": "Inclusion Criteria:\n\nPart 1:\n\n\* healthy participants\n\* has a Body Mass Index (BMI) =\\< 30 kg/m\\^2\n\* female of reproductive potential remains abstinent or uses two acceptable methods of birth control from 2 weeks before first allergen challenge to 2 weeks after last allergen challenge; alternatively hormonal contraception may be used.\n\nPart 2:\n\n\* has a Body Mass Index (BMI) =\\< 38 kg/m\\^2\n\* has a clinical history of allergic rhinitis/rhinoconjunctivitis to HDM for at least one year, and used medication to relieve symptoms within the last year\n\* does not have asthma, or has mild controlled asthma not requiring regular use over the 12 months prior to screening of any corticosteroids\n\* female of reproductive potential remains abstinent or use two acceptable methods of birth control from 2 weeks before first allergen challenge to at least 2 weeks after last allergen challenge or last dose of study drug, whichever is longer\n\* has not smoked or used tobacco for the prior 6 months, and agrees not to during study\n\nExclusion Criteria:\n\nParts 1 and 2:\n\n\* is experiencing at the first NAC visit, symptoms from an upper or lower respiratory tract infection (viral or bacterial)\n\* has participated within the prior 3 months in another investigational study (that included an investigational drug or agent)\n\* is directly associated with the administration of the study or is related to the investigational study staff\n\* is mentally or legally incapacitated, has significant emotional problems or has a history of clinically significant psychiatric disorder within the past 5 years\n\* has a history of clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary or major neurological (including stroke and chronic seizures) abnormalities or diseases\n\* has a history of cancer\n\* has a history of significant intolerability to drugs or food\n\* is positive for hepatitis B surface antigen, hepatitis C antibodies or HIV\n\* had major surgery or lost 1 unit (500 mL) of blood within the prior 4 weeks\n\* has a clinical history of chronic sinusitis during the prior 2 years\n\* has any nasal condition (e.g. nasal polyposis) that could confound efficacy or safety assessments\n\* is pregnant or expects to conceive during the study period\n\* is a nursing mother\n\* consumes more than 3 glasses of alcoholic beverages per day\n\* regularly uses any illicit drug, or has a history of drug or alcohol abuse within the prior 6 months\n\nPart 2 only:\n\n\* is experiencing allergic rhinoconjunctivitis exacerbation at Screening NAC\n\* consumes excessive daily amounts of caffeinated beverages\n\* has a known history of allergy, hypersensitivity or intolerance to investigational medicines\n\* is sensitized and regularly exposed to animal dander and molds in the home or workplace in a manner that might interfere with the study in the opinion of the investigator\n\* is sensitized and regularly exposed to seasonal allergens such as Birch or grass pollen (sensitized but out of season is acceptable however)\n\* has a history of chronic urticaria and/or angioedema within the prior 2 years\n\* has had previous immunotherapeutic treatment with any HDM allergen for more than 1 month during the prior 3 years\n\* is receiving any specific immunotherapy within prior 60 days\n\* has a history of anaphylaxis with cardiorespiratory symptoms with prior immunotherapy due to an unknown cause or an inhalant allergen",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
Based on the information provided, the clinical trial seems to focus on participants who have specific criteria related to allergic rhinitis/rhinoconjunctivitis and does not specifically involve genetic mutations like the ALK gene mutation. The eligibility criteria list does not include or exclude participants with an ALK gene mutation specifically.  
  
The trial's inclusion and exclusion criteria appear to be largely related to allergic conditions, asthma status, other health conditions, behavioral habits (like smoking and alcohol consumption), and certain medical histories. There is no mention of genetic conditions or mutations, including ALK gene mutations.  
  
Therefore, having an ALK gene mutation does not appear to be a factor that would make a person ineligible for participation in this clinical trial based on the provided criteria. However, eligibility can also depend on other factors not mentioned here, so it would be important for the patient to discuss with the clinical trial team or their healthcare provider to confirm eligibility.