# Clinical Trials Data KIT - Document 5

# An Open Label, Prospective, One Arm, Feasibility, Study for The Use of Halevy Kit for the Treatment of Perianal Fistulas in Patients With Crohn's Disease

## Clinical Trial: https://clinicaltrials.gov/study/NCT00653094

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Male and Female age greater than 18\n\* Patients suffering from Crohn's disease\n\* Patients with any number of simple or complex fistulas who require surgical intervention, requiring the insertion of a drain (Seton) into the fistula tract, and/or injection of biologic adhesive, or an anal fistula plug\n\* Able and willing to sign an informed consent\n\* Patient will be available for follow up.\n\nExclusion Criteria:\n\n\* Pregnant or lactating woman. Woman of childbearing potential will undergo a pregnancy test at the beginning of the trial\n\* Known immunodeficiency.\n\* Exclusion Criteria for injecting biologic adhesive:\n\n \* Known allergy to fibrin glue or one of its components.\n \* An undrained perianal abscess, diagnosed by a physical examination or imaging methods.\n\* Known Alcohol or drug abuse",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
Based on the provided clinical trial eligibility criteria, a patient with a KIT gene mutation would not be automatically excluded or included solely based on this genetic mutation. The key inclusion and exclusion criteria do not mention the KIT gene mutation as a factor. The primary factors for eligibility focus on age, the presence of Crohn's disease with specific fistula requirements, consent and availability, and specific exclusions like pregnancy, known immunodeficiency, certain allergies, and substance abuse.  
  
Therefore, the presence of a KIT gene mutation would not affect eligibility unless it is related to another listed criterion, such as causing an immunodeficiency. It's always advisable for patients to discuss these details with the clinical trial investigators for clarification regarding their specific medical conditions.