# 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:  
This trial description does \*\*not\*\* mention KIT gene mutations as either an inclusion or exclusion criterion. Therefore, we cannot determine eligibility based on this information alone. A patient with a KIT gene mutation \*could\* potentially be eligible if they meet all other inclusion criteria and none of the exclusion criteria. However, the presence of the mutation is not explicitly addressed.