# Clinical Trials Data KIT - Document 44

# Study of STI571 in the Treatment of Patients With Idiopathic Hypereosinophilic Syndrome (HES) and Eosinophilic Leukemias

## Clinical Trial: https://clinicaltrials.gov/study/NCT00276926

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Presence of primary or secondary HES\n2. Not a candidate for allogeneic bone marrow transplantation.\n3. ECOG performance score of 0, 1, 2 or 3 (Karnofsky performance score \\> 40%).\n4. Life expectancy \\> 4 weeks.\n5. Adequate hepatic and renal function, as defined by serum transaminases \\< 2.5x upper limits of normal (ULN), bilirubin \\< 1.5x ULN, and creatinine \\< 1.5x ULN.\n6. Age 18 years or greater.\n7. Post-menopausal, surgically sterile, or taking effective contraception in female patients.\n8. Documentation of written informed consent to participate in the trial.\n9. Willingness and ability to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.\n\nExclusion Criteria:\n\nThe presence of any of the following will exclude a subject from study enrollment:\n\n1. Patients with clear evidence of secondary hypereosinophilia.\n2. Acute myeloblastic leukemia with inv(16) positive blast or\n3. CBFb-MYH11 transcripts positive leukemia\n4. Lack of recovery from the acute toxic effects of previous chemotherapy \\[to common toxicity criteria (CTC) grade \\> 1\\] with the exception of chemotherapy-induced alopecia.\n5. Treatment with any investigational agent within 4 weeks prior to study therapy.\n6. Major surgeries within 4 weeks from study start or not fully recovered from any previous surgical procedure.\n7. Presence of any medical or psychiatric condition which may limit full compliance with the study or increase the risk associated with study participation or study drug administration, including but not limited to\n8. Presence of central nervous system (CNS) illness and involvement of disease.\n9. Active uncontrolled bacterial infection.\n10. Known human immunodeficiency virus (HIV) infection.\n11. Grade 3 or 4 bleeding.\n12. Significant cardiovascular disease (i.e., uncontrolled arrhythmias, unstable angina), or a major thromboembolic event (myocardial infarction, stroke, transient ischemic attack, pulmonary embolism, or non-catheter-related deep-vein thrombosis) in the last 6 months. Due to the low cardiac toxicity profile of Glivec, it is not considered an exclusion criterion if the presence of severe complications to the viscera, among which cardiopathies, and in particular endomyocardial fibrosis, is due or considered to be due to HES.\n13. Increased blood eosinophil counts due to the presence of physician-diagnosed asthma. However, due to low pulmonary toxicity profile of Glivec, it is not considered an exclusion criterion, if HES is associated with asthma, and the presence of severe complications damaging the lungs, are considered due to HES.\n14. Pregnancy or breast-feeding.\n15. Malabsorption syndromes",  
 "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 clinical trial information provided, there is no mention of a KIT gene mutation as a specific criterion for inclusion or exclusion. The eligibility criteria primarily focus on the diagnosis and condition of hypereosinophilic syndrome (HES), performance status, organ function, and other medical conditions. Unless the presence of a KIT gene mutation somehow correlates with the exclusion criteria listed (such as a specific type of leukemia or a condition that could be a secondary cause of HES), it does not appear that a KIT mutation alone would disqualify a patient from participation.  
  
Therefore, a patient with a KIT gene mutation might still be eligible for this trial as long as they meet all the inclusion criteria and none of the exclusion criteria apply to them. It would be advisable for the patient to discuss their specific case with the trial investigators to confirm eligibility.