# Clinical Trials Data KIT - Document 6

# Phase II Study of Anlotinib Versus Sunitinib in Patients With Advanced Renal Cell Carcinoma（RCC）

## Clinical Trial: https://clinicaltrials.gov/study/NCT02072031

"eligibilityCriteria": "Inclusion Criteria:\n\n\* 1.Patients with histologically confirmed advanced renal cell carcinoma including clear cell component and not available for surgery\n\* 2.Without drug treatment for RCC or chemotherapy/cytokine therapy failure or resistant patients)\n\* 3.With measurable disease (using RECIST1.1)\n\* 4.18-75years,ECOG PS:0-1,Life expectancy of more than 3 months\n\* 5.Other cytotoxic drugs,radiation therapy,or surgery\u22654 weeks\n\* 6.main organs function is normal\n\* 7.Signed and dated informed consent\n\nExclusion Criteria:\n\n\* 1.Previously received targeted therapy of the metastatic renal cell carcinoma (such as sunitinib, Sorafenib)\n\* 2.patients has many influence factors toward oral medications\n\* 3.Known brain metastases\n\* 4.patients with severe and failed to controlled diseases,including: suboptimal blood pressure control;suffering from myocardial ischemia or above grade I myocardial infarction, arrhythmias and Class I heart failure;activity or failure to control severe infections;liver disease such as cirrhosis, decompensated liver disease, chronic active hepatitis;poorly controlled diabetes (FBG)\\>10mmol/L);urine protein\u2265++,etc.\n\* 5.patients failed to heal wounds or fractures for Long-term\n\* 6.patients occurred venous thromboembolic events within 6 months\n\* 7.patients has HIV-positive or organ transplantation",  
 "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 eligibility criteria for the clinical trial, there is no specific mention of exclusion based on the presence of a KIT gene mutation. The criteria focus on the type and stage of renal cell carcinoma, previous treatments received, general health status, and specific health conditions.  
  
Assuming the patient meets all other inclusion criteria—such as having advanced renal cell carcinoma, being within the specified age range, having a good performance status (ECOG 0-1), and having no severe uncontrolled diseases or recent venous thromboembolic events—they would be eligible unless their KIT gene mutation is accompanied by an exclusion factor mentioned (like brain metastases or severe cardiovascular conditions).  
  
Therefore, a patient with a KIT gene mutation could be eligible for the trial, provided they satisfy all other criteria and the mutation does not result in any listed exclusion factors. However, it would be essential for the patient or their healthcare provider to consult with the trial coordinators for clarification specific to genetic mutations if they have any concerns.