# 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:  
The provided information doesn't explicitly state whether a KIT gene mutation includes or excludes a patient. The criteria focus on:  
  
\* \*\*Advanced renal cell carcinoma (RCC) with a clear cell component:\*\* The patient needs to have this specific type of RCC.  
\* \*\*Treatment history:\*\* No prior targeted therapy for metastatic RCC (like sunitinib or sorafenib) is allowed. Prior chemo/cytokine therapy is okay.  
\* \*\*Measurable disease:\*\* The disease must be measurable according to RECIST1.1 criteria.  
\* \*\*Age and general health:\*\* 18-75 years old, ECOG performance status 0-1, life expectancy > 3 months, and normal organ function.  
\* \*\*No significant comorbidities:\*\* Controlled blood pressure, no serious heart conditions, no active severe infections, no severe liver disease, controlled diabetes, no excessive protein in urine, healed wounds/fractures, no recent venous thromboembolic events, and no HIV or organ transplant.  
  
\*\*A KIT mutation is not mentioned in the inclusion or exclusion criteria.\*\* Therefore, based solely on this information, it's \*unknown\* whether a patient with a KIT mutation would be eligible. Further information would be needed from the trial investigators. The presence of a clear cell component is essential, as some KIT mutations are associated with non-clear cell RCC, which would likely exclude them.