# Clinical Trials Data KIT - Document 4

# A Study of Famitinib in Patients With Advanced or Metastatic Gastroenteropancreatic Neuroendocrine Tumor

## Clinical Trial: https://clinicaltrials.gov/study/NCT01994213

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Unresectable advanced or metastatic, histologically-confirmed, gastroenteropancreatic neuroendocrine tumor. Tumors must be considered well-differentiated grade G1 or grade G2 in accordance with WHO 2010 classification.\n\* Must have at least one measurable disease by RECIST1.1 criteria(tumour lesions \u226510mm in longest diameter, malignant lymph nodes \u226515mm in short axis, scanning layer \u2264 5 mm).\n\* First-line therapy or second-line treatment (second-line treatment i.e. chemotherapy or cytokine therapy as first-line treatment failure or resistant patients).\n\* No previously received targeted therapy of gastroenteropancreatic neuroendocrine tumor (such as everolimus, sunitinib, or other tyrosine kinase or VEGF inhibitor treatment).\n\* Age between 18 and 75 years.\n\* ECOG Performance status \u2264 1.\n\* Ability to understand and the willingness to sign a written informed consent document.\n\nExclusion Criteria:\n\n\* Patients with small-cell carcinoma, pheochromocytoma, paraganglioma or Merkel cell carcinoma\n\* Past or suffering from other cancer, but other than cure basal cell carcinoma and cervical carcinoma in situ\n\* Participated in other clinical trials within four weeks\n\* Concurrent therapy with somatostatin analogs(such as octreotide, lanreotide,etc.)\n\* A variety of factors that affect the oral medication (such as inability to swallow, gastrointestinal resection, chronic diarrhea and intestinal obstruction)\n\* Known brain metastases, spinal cord compression, cancer, meningitis, or screening CT or MRI examination revealed brain or leptomeningeal disease\n\* Subjects received surgery, chemotherapy, radiation therapy, cytokines treatment caused the damage has not been restored, the time interval \u2264 4 weeks, and the wound has not completely healed\n\* Participants have inadequate organ and marrow function as defined below:\n\n \* hemoglobin \\< 90g/L\n \* platelets \\< 100\u00d710\\^9/L\n \* neutrophils \\< 1.5\u00d710\\^9/L\n \* total bilirubin \u2265 1.25\u00d7ULN\n \* serum transaminase(ALT and AST ) \u2265 1.5\u00d7ULN (If liver metastases are present, serum transaminase\u2265 2.5\u00d7ULN)\n \* creatinine clearance rate \u2264 60ml/min\n \* cholesterol \u2265 1.5\u00d7ULN and triglyceride\u2265 2.5 x ULN,\n \* LVEF: \\< 50% by Color Doppler Ultrasonography\n\* Patients with uncontrollable hypertension after using single agent therapy (systolic blood pressure\\> 140 mmHg, diastolic blood pressure\\> 90 mmHg). Patients with more than Class I, myocardial ischemia or myocardial infarction, arrhythmia (including QT interval \u2265 450ms for male and 470ms for female) and class I heart failure.\n\* Urine protein \u2265 + + and confirmed the 24-hour urinary protein\\>1.0 g\n\* Long-term untreated wounds or fractures\n\* Coagulopathy with bleeding tendency (such as active peptic ulcer)\n\* Previous artery / venous thromboembolic events, such as cerebrovascular accident (including transient ischemic attacks), deep vein thrombosis and pulmonary embolism\n\* Application of anticoagulants or vitamin K antagonists such as warfarin, heparin or its analogues; If the prothrombin time international normalized ratio (INR) \u2264 1.5, with the purpose of prevention, the use of small doses of warfarin (1mg orally, once daily) or low-dose aspirin (less than 100mg daily) is allowed\n\* Female: All subjects who are not surgically sterile or postmenopausal must agree and commit to the use of a reliable method of birth control for the duration of the study and for 6 months after the last dose of test article. Child bearing potential, a negative urine or serum pregnancy test result before initiating Famitinib. Male: All subjects who are not surgically sterile or postmenopausal must agree and commit to the use of a reliable method of birth control for the duration of the study and for 6 months after the last dose of test article.\n\* Preexisting thyroid dysfunction, even using medical therapy, thyroid function cannot maintain in the normal range\n\* Abuse of psychiatric drugs or dysphrenia\n\* Immunodeficiency: HIV positive, or other acquired immunodeficiency, congenital immunodeficiency, or organ transplantation\n\* Evidence of significant medical illness that in the investigator's judgment will substantially increase the risk associated with the subject's participation in and completion of the study.",  
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"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 eligibility criteria provided for this clinical trial, there are no specific mentions of a KIT gene mutation as an exclusion criterion. The inclusion and exclusion criteria focus on the type of tumor, previous treatments, current health status, and other medical conditions.  
  
Thus, the presence of a KIT gene mutation alone would not necessarily make a patient ineligible for this trial unless it is associated with other exclusion criteria, such as the type of neuroendocrine tumor (small-cell carcinoma, pheochromocytoma, paraganglioma, or Merkel cell carcinoma) or concurrent medical treatments that are not permitted.  
  
If a patient with a KIT gene mutation meets all the other inclusion criteria and does not fall under any of the exclusion criteria, they would likely be eligible for participation in the trial, provided the mutation does not impact their ability to meet these criteria. It's important for the patient's healthcare provider or the trial investigator to carefully review all criteria in conjunction with any specific genetic mutations to make a final determination.