# Clinical Trials Data KRAS - Document 17

# PiCCA Study (Panitumumab in Combination With Cisplatin/Gemcitabine)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01320254

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Signed,dated informed consent before start of specific protocol procedures\n\* Histologically/cytologically documented diagnosis of cholangiocarcinoma or gall bladder carcinoma\n\* At least one measurable site of disease following RECIST V. 1.1 criteria\n\* Wild-type KRAS status as assessed by standardized PCR\n\* Unresectable, locally advanced or metastatic disease\n\* Age \\> 18 years old\n\* ECOG Performance Status 0 or 1\n\* Life expectancy of at least 12 weeks\n\* Adequate bone marrow, liver (with stenting for any obstruction, if required) and renal function (lab. assessment within 7 days prior to screening):\n\* Hemoglobin \\> 10.0 g/dl\n\* Leukocyte count \\> 3.000/mm3 ; absolute neutrophil count (ANC) \\> 1.500/mm3\n\* Platelet count 100.000/mm\u00b3\n\* Total bilirubin \\< 5,0 times the upper limit of normal\n\* ALT and AST \\< 3 x upper limit of normal\n\* Alkaline phosphatase \\< 5 x ULN\n\* PT-INR/PTT \\< 1.5 x upper limit of normal \\[Patients who are being therapeutically anticoagulated with an agent such as coumarin or heparin will be allowed to participate provided that no prior evidence of underlying abnormality in these parameters exists.\\]\n\* Serum creatinine \\< 1.5 x upper limit of normal and creatinine clearance \\> 60 ml/min\n\* Magnesium \u2265 lower limit of normal; calcium \u2265 lower limit of normal\n\* The patient is willing and able to comply with the protocol for the duration of the study, including hospital visits for treatment and scheduled follow-up visits and examinations\n\* Negative pregnancy test performed within 7 days prior to the start of treatment, and willingness to use highly effective methods of contraception (per institutional standard) during treatment and for 6 months (male or female) after the end of treatment (adequate: oral contraceptives, intrauterine device or barrier method in conjunction with spermicidal jelly)\n\nExclusion Criteria:\n\n\* KRAS mutation\n\* Clinically significant cardiovascular disease (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) \u2264 1 year before enrollment\n\* History of interstitial lung disease, e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan.\n\* History of HIV infection or chronic hepatitis B\n\* Active clinically serious infections (\\> grade 2 NCI-CTC version 3.0)\n\* Pre-existing neuropathy \\> grade 1 (NCI CTCAE), except for loss of tendon reflex (patellar tendon reflex)\n\* Symptomatic or known brain metastases.A scan to confirm the absence of brain metastases is not required -Patients with seizure disorder requiring medication (such as steroids or anti- epileptics)\n\* History of organ allograft\n\* Patients with evidence or history of bleeding diathesis\n\* Patients undergoing renal dialysis\n\* Patients with second primary cancer,except adequately treated basal skin cancer or carcinoma in-situ of the cervix\n\* Any condition that is unstable or could jeopardize the safety of the patient and their compliance in the study\n\* No prior anti-cancer chemotherapy,radiotherapy(excluding palliative radiotherapy administered more than 4 weeks prior to study entry),endocrine or immunotherapy\n\* Investigational drug therapy outside of this trial during or within 4weeks of study entry\n\* Major surgery within 4 weeks of starting the study and patients must have recovered from effects of major surgery\n\* Prior anti-EGFR therapy\n\* Autologous bone marrow transplant or stem cell rescue within 4 months of study\n\* Breast-feeding patients\n\* Substance abuse, medical, psychological or social conditions that may interfere with the patient's understanding of the informed consent procedure, participation in the study or evaluation of the study results",  
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"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a KRAS gene mutation be eligible for the clinical trial?

Answer:  
No. The inclusion criteria specifically require "Wild-type KRAS status" and the exclusion criteria list "KRAS mutation". Therefore, a patient with a KRAS mutation would \*not\* be eligible for this trial.