# Clinical Trials Data KRAS - Document 16

# A Study of Perioperative Chemotherapy Plus Panitumumab in Patients With Colorectal Cancer Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01260415

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients must have histologically or cytologically confirmed colorectal cancer with available tissue to test for K-RAS mutation. Biopsy is required if no archived tissue is available. K-RAS mutation status must be confirmed prior to registration. Only patients with K-RAS wild-type cancers are eligible.\n\* Patients must have measurable disease, defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded) as \\>20 mm with conventional techniques or as \\>10 mm with spiral CT scan.\n\* Patients must have resectable hepatic colorectal metastases.\n\* Patients may have synchronous unresected primary disease upon registration. Primary must be resectable, either at same laparotomy or at separate laparotomy from liver resection.\n\* Age \\>18 years.\n\* Patients must have Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1.\n\* Patients must have normal organ and marrow function as defined below:\n\nleukocytes \\> 3,000/mcL absolute neutrophil count \\>1,500/mcL platelets \\>100,000/mcL hemoglobin \\> 90 g/L total bilirubin \\< 2 x upper limit of normal (\\< 1.5 x ULN for FOLFIRI), AST(SGOT) and ALT(SGPT)\\< 5 x upper limit of normal (\\< 3 x ULN for FOLFIRI);creatinine within normal institutional limits OR- creatinine clearance \\>50 mL/min/1.73 m2 for patients with creatinine levels above institutional normal\n\n\* Appropriate imaging investigations, including CT or MRI of chest/abdomen/pelvis. Other scans if clinically indicated may be performed. All imaging studies must be performed within 28 days of study entry.\n\* Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study and for a period of six months after cessation of study therapy. Should a woman become pregnant or suspect she is pregnant while participating in this study, she must inform her treating physician immediately.\n\* Ability to understand and the willingness to sign a written informed consent document.\n\nExclusion Criteria\n\n\* Patients must have had no previous systemic treatment in the adjuvant or metastatic setting within 6 months of registration.\n\* Patients may not have had prior treatment with an EGFR antagonist.\n\* Patients may not have a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid malignancies curatively treated with no evidence of disease for \u2265 5 years.\n\* Patients may not have extrahepatic metastatic disease. Patients who have had prior surgical resection for hepatic metastases or extrahepatic disease (eg. pulmonary metastases) are also excluded from this study.\n\* Patients may not have pre-existing chronic hepatic disease (eg. cirrhosis, chronic active hepatitis B or C)\n\* History of allergic reactions, or intolerance, attributed to compounds of similar chemical or biologic composition to 5-fluorouracil, oxaliplatin, or panitumumab.\n\* Patients being considered for irinotecan must not have a history of Gilbert's syndrome.\n\* Patients may not have uncontrolled inter-current illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.\n\* HIV-positive patients on combination antiretroviral therapy are ineligible because of the potential for pharmacokinetic interactions with the agents used in this study. In addition, these patients are at increased risk of lethal infections when treated with marrow-suppressive therapy.\n\* Patients with active cardiovascular disease, i.e., unstable angina, New York Heart Association grade II or greater congestive heart failure, serious cardiac arrhythmia requiring medications, or grade II or greater peripheral vascular disease. In addition, patients with arterial or venous thrombosis, myocardial infarction, and cerebral vascular accidents (stroke / transient ischemic attach (TIA)) within 6 months prior to study entry will be excluded.\n\* Patients with a history of interstitial pneumonitis or pulmonary fibrosis will be excluded.\n\* Organ allografts requiring immunosuppressive therapy.",  
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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 explicitly state that "Only patients with K-RAS wild-type cancers are eligible." This means patients with a KRAS mutation are \*not\* eligible for this trial.