# Clinical Trials Data KRAS - Document 31

# Achievement of Improved Survival by Molecular Targeted Chemotherapy and Liver Resection for Not Optimally Resectable Colorectal Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01836653

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Histopathologically confirmed colorectal cancer (adenocarcinoma) excluding vermiform appendix cancer and proctos cancer.\n2. RAS wild type\n3. Synchronous\\\* or metachronous liver limited meitastasis with no extrahepatic desiease\n\n \* shychronous liver limited metastasis with primary lesion less than two thirds of the circumference\n \* patients with primary lesion more than two thirds of the circumference can be enrolled after primary resection\n4. Patients who has one or more lesion(s) of diameter 1 cm or larger (RECEST v1.1) be able to assess continuously on the basis of the protocol by contrast enhanced CT or contrast enhanced MRI of the liver:\n\n(1)Liver metastases 5 or more (2)Liver metastases with 5 cm or larger in greatest dimension (3)Unresectable considering remaining hepatic function (4)Invasion into all hepatic veins or inferior vena cava (5)Invasion into both right and left hepatic arteries or portal veins 5.No prior chemotherapy for colorectal cancer including hepatic arterial infusion. Excluding postoperative and preoperative chemoradiotherapy except for rectal cancer with synchronous liver metastases. Patients received postoperative chemotherapy containing oxaliplatin have to be enrolled after 24 weeks from the last oxaliplatin administration.\n\n6.No previous treatment including ablation therapy, cryotherapy and chemotherapy for metastases 7.Age at enrollment is \\>=20 and =\\<80 years 8.The Eastern Cooperative Oncology Group (ECOG) Performance Status 0-1 9.Life expectancy from the day of enrollment is 3 months or longer 10.Major organ functions less than 14 days prior to entry meet the following criteria.\n\n1. Neu \\>= 1500/mm3\n2. Pt \\>= 10.0x10\\^4/mm3\n3. Hb \\>= 9.0 g/dL\n4. T-bil =\\< 2.0 mg/dL\n5. AST and ALT =\\< 200 IU/L\n6. sCr =\\< 1.20 mg/dL\n7. INR \\< 1.5\n8. Proteinuria =\\< 2+ 11.Written informed consent\n\nExclusion Criteria:\n\n1. Previously experienced severe allergic reaction to drugs\n2. Receiving anti-platelet drugs (aspirin \\>= 325 mg/day) or NSAIDs\n3. Receiving chronic systemic corticosteroid treatment\n4. Surgery/ biopsy with skin incision or traumatic injury with suture less than 14 days prior to entry. Excluding, suture for implanted venous reservoirs with catherter is allowed.\n5. Severe postoperative complications (e.g. postoperative infection, anastomic dehiscence or paralytic ileus)\n6. Diagnosed as hereditary colorectal cancer\n7. Active other malignancies\n8. Cerebrovascular disease or symptoms less than 1 year prior to entry\n9. Pleural effusion, ascites or cardiac effusion requiring drainage\n10. Hemorrhage/bleeding, paralytic ileus, obstruction or ulceration of gastrointestinal tract\n11. Perforation of gastrointestinal tract less than 1 year prior to entry\n12. Presence of active infection\n13. HBs antigen or HCV antibody positive\n14. Uncontrolled comorbidity including hypertension, diabetes, arrhythmia, or other diseases (such as cardiac disorder, interstitial pneumonia or renal disorder)\n15. Presence of \\>= grade 2 diarrhea\n16. Presence of \\>= grade 1 peripheral neuropathy\n17. Pregnant or lactating women. Women and men with childbearing potential unwilling to use effective means of contraception\n18. Psychosis or psychiatric symptoms who are not able to comply with the protocol\n19. Any other medical conditions disable to comply with the protocol",  
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 "sex": "ALL",  
 "minimumAge": "20 Years",  
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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. Inclusion criteria #2 explicitly states that patients must be "RAS wild type." A KRAS mutation means the patient is \*not\* RAS wild type, therefore they would be ineligible for this trial.