# Clinical Trials Data KRAS - Document 7

# Efficacy of FOLFOX Alone, FOLFOX Plus Bevacizumab and FOLFOX Plus Panitumumab in Patients With Resectable Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01508000

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically proven CRC with 1 to 8 metachronous or synchronous liver metastases considered to be completely resectable.\n\* Primary tumor (or liver metastasis) of CRC must be KRAS and NRAS status \"wild type\".\n\* Patients must have undergone complete resection (R0) of the primary tumor at least 4 weeks before randomization. Or for patients with synchronous metastases the primary tumor can be resected (R0) at the same time as the liver metastases if: the patient has a non-obstructive primary tumor and is able to receive preoperative chemotherapy (3-4 months) before surgery.\n\* Measurable hepatic disease by RECIST version 1.1.\n\* Patients must be 18 years old or older.\n\* A WHO performance status of 0 or 1. Radiotherapy alone is allowed if given pre or post protocol treatment.\n\* Previous adjuvant chemotherapy for primary CRC is allowed if completed at least 12 months before inclusion in this study.\n\* All the following tests should be done within 4 weeks prior to randomization:\n\* Absolute neutrophil count \u2265 1.5 x 109/L, platelets \u2265 100 x 109/L, hemoglobin \u2265 9 g/dL and white blood cell count (WBC) \u2265 3 x 109/L.\n\* Serum creatinine \u2264 1.5 times the upper limit of normal (ULN) (to exclude severe renal impairment); no significant proteinuria (urine protein \\< 1g/24 hours urine collection) OR urine protein/creatinine ratio \\< 1.0 OR 1+ proteinuria on urine dipstick.\n\* Absence of major hepatic insufficiency (bilirubin \u2264 1.5 x ULN and aspartate aminotransferase (ASAT) and alanine aminotransferase (ALAT) \u2264 5 x ULN).\n\* Magnesium \u2265 lower limit of normal (LLN)\n\* Patients with a buffer range from the normal values of +/- 5% for hematology and +/- 10% for biochemistry are acceptable. This will not apply for Renal Function, including Creatinine.\n\* Women of child bearing potential (WOCBP) must have a negative serum (or urine) pregnancy test within 14 days prior to the first dose of study treatment.\n\* Patients of childbearing / reproductive potential should use adequate birth control measures, as defined by the investigator, during the study treatment period and for at least 6 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly.\n\* Female subjects who are breast feeding should discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment.\n\* Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.\n\nExclusion Criteria:\n\n\* Evidence of extra-hepatic metastasis (of CRC).\n\* Previous chemotherapy for metastatic disease or surgical treatment (e.g. surgical resection or radiofrequency ablation) for liver metastasis.\n\* Previous exposure to EGFR or VEGF/VEGFR targeting therapy within the last 12 months.\n\* Major surgical procedure, open biopsy, or significant traumatic injury within 4 weeks prior to randomization.\n\* Regular use of aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).\n\* Bleeding diathesis (e.g. hemoptysis of \u2265 1/2 teaspoon or 2.5mL), coagulopathy, or need for administration of full-dose anti-coagulant(s).\n\* Clinically significant cardiovascular disease, including: uncontrolled hypertension, New York Heart Association (NYHA) class II-IV heart failure, myocardial infarction or unstable angina pectoris, cerebrovascular accident or transient ischemic attack within the past 12 months, peripheral vascular disease \u2265 grade 2, serious cardiac arrhythmia requiring medication and other clinically significant cardiovascular disease.\n\* Peripheral neuropathy \\> grade 1 (Common Terminology Criteria for Adverse Events, v4.0) serious wound complications, ulcers, or bone fractures.\n\* Symptomatic diverticulitis or active or uncontrolled gastroduodenal ulceration.\n\* History or evidence of interstitial lung disease (e.g. pneumonitis, pulmonary fibrosis)\n\* Significant disease that, in the investigator's opinion, would exclude the patient from the study. Including known allergy or any other adverse reaction to any of the study drugs (including any of the excipients) or to any related compound, including hypersensitivity to Chinese hamster ovary (CHO) cell products or other recombinant human or humanized antibodies.\n\* Presence of any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.\n\* Participation in another clinical study (except sub studies of this protocol) within the 30 days before randomization and during this study.",  
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 "minimumAge": "18 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. The inclusion criteria specifically state that the primary tumor or liver metastasis must be KRAS and NRAS "wild type". This means the patient \*cannot\* have a KRAS mutation to be eligible.