# Clinical Trials Data KRAS - Document 26

# Efficacy of FOLFOX Versus FOLFOX Plus Aflibercept in K-ras Mutant Patients With Resectable Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01646554

"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 status \"mutant\"\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 surgery1.\n\* Measurable hepatic disease by RECIST version 1.1\n\* Patients must be 18 years old or older\n\* A World Health Organization (WHO) performance status of 0 or 1\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\* Hematological status: neutrophils (ANC) = 1.5x10 9/L; platelets = 100x10 9/L; haemoglobin = 9g/dL\n\* Serum creatinine = 1.5 times the upper limit of normal (ULN)\n\* Proteinuria \\< 2+ (dipstick urinalysis) or =1g/24hour.\n\* Liver function: serum bilirubin = 1.5 x upper normal limit (ULN), alkaline phosphatase \\< 5xULN\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\* Absence 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\* Patient should be willing and able to comply with protocol requirements\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. Radiotherapy alone is allowed if given pre or post protocol treatment\n\* Previous exposure to 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\* Gilbert's syndrome\n\* History of myocardial infarction and/or stroke within 6 months prior to randomization\n\* Uncontrolled hypertension (defined as systolic blood pressure \\>150 mmHg and/or diastolic blood pressure \\> 100 mmHg), or history of hypertensive crisis, or hypertensive encephalopathy\n\* History or evidence upon physical examination of CNS metastasis\n\* Bowel obstruction\n\* Uncontrolled hypercalcemia\n\* Pre-existing permanent neuropathy (NCI grade = 2)\n\* Known allergy to any excipient to study drugs",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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:  
Based on the inclusion criteria for the clinical trial, a patient with a KRAS gene mutation in their primary tumor or liver metastasis of colorectal cancer (CRC) would be eligible for this clinical trial. One of the key inclusion criteria explicitly states that the primary tumor (or liver metastasis) of CRC must be KRAS status "mutant". Therefore, having a KRAS gene mutation is actually a requirement for participation in this trial.