# Clinical Trials Data KRAS - Document 8

# Clinical Trial of Combination Chemotherapy With Aflibercept in Patients With Advanced Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02129257

"eligibilityCriteria": "Inclusion Criteria\n\n\* Histologically proven adenocarcinoma of the colon and/or rectum\n\* Metastatic disease confirmed clinically/radiologically\n\* Signed written informed consent\n\* No prior therapy for metastatic disease\n\* Duly documented inoperable metastatic disease, ie not suitable for complete curative surgical resection\n\* At least one measurable or evaluable lesion as assessed by Computed Tomography (CT) scan or MRI (Magnetic Resonance Imaging) according to Response Evaluation Criteria In Solid Tumors (RECIST) v1.1\n\* Age \u226518 years\n\* Eastern Cooperative Oncology Group (ECOG) Performance status (PS) 0-2\n\* Adequate hematological status:\n\n \* neutrophils (ANC) \u22651.5x109/L\n \* platelets \u2265100x109/L\n \* haemoglobin \u22659g/dL\n\* Adequate renal function: serum creatinine level \\<1.5 mg/dl and Glomerular Filtration Rate\\>50 ml/min by Cockroft/Gault formula\n\* Adequate liver function:\n\n \* serum bilirubin \u22641.5 x upper normal limit (ULN)\n \* alkaline phosphatase\n \* aspartate aminotransferase (AST)\n \* alanine aminotransferase (ALT) \\< 5 x ULN\n\* Proteinuria \\<2+ (dipstick urinalysis) or \u22641g/24hour\n\* Regular follow-up feasible\n\* Baseline evaluations performed before registration: clinical and blood evaluations no more than 2 weeks (14 days) prior to registration, tumor assessment (chest X-ray, CT-scan or MRI, evaluation of non-measurable lesions) no more than 3 weeks (21 days) prior to registration\n\* First course of treatment planned less than 1 week (7 days) after registration\n\* For female patients of childbearing potential, negative serum pregnancy test within 1 week (7 days) prior of starting study treatment\n\* Female patients must commit to using reliable and appropriate methods of contraception until at least three months after the end of study treatment (when applicable). Male patients with a partner of childbearing potential must agree to use contraception in addition to having their partner use another contraceptive method during the trial.\n\nExclusion Criteria\n\n\* Exclusive presence of bone metastasis only\n\* Uncontrolled hypercalcemia\n\* Uncontrolled hypertension (defined as systolic blood pressure \\>150 mmHg and/or diastolic blood pressure \\>100 mmHg despite medical therapy), or history of hypertensive crisis, or hypertensive encephalopathy\n\* Concomitant unplanned antitumor therapy (e.g. chemotherapy, molecular targeted therapy, immunotherapy)\n\* Treatment with any other investigational medicinal product within 28 days prior to study entry\n\* Other serious and uncontrolled non-malignant chronic disease\n\* History or presence of Central Nervous System (CNS) metastasis unless adequately treated (e.g. non irradiated CNS metastasis, seizures not controlled with standard medical therapy)\n\* Gilbert's syndrome\n\* Intolerance to atropine sulfate or loperamide\n\* Known dihydropyrimidine dehydrogenase deficiency\n\* Treatment with Cytochrome P450 3A4 (CYP3A4) inducers unless discontinued \\> 7 days prior to randomization\n\* Any of the following in 3 months prior to inclusion: grade 3-4 gastrointestinal bleeding (unless due to resected tumor), treatment resistant peptic ulcer disease, erosive esophagitis or gastritis, infectious or inflammatory bowel disease, or diverticulitis\n\* Other concomitant or previous malignancy, except:\n\n \* adequately treated in-situ carcinoma of the uterine cervix\n \* basal or squamous cell carcinoma of the skin\n \* cancer in complete remission for \\>5 years\n\* Any other serious and uncontrolled non-malignant disease, major surgery or traumatic injury within the last 28 days\n\* Pregnant or breastfeeding women\n\* Patients with known allergy to any excipients to study drugs\n\* History of myocardial infarction and/or stroke or other arterial thrombotic events or pulmonary embolism or unstable angina pectoris within 6 months prior to registration\n\* Poorly controlled cardiac arrhythmias\n\* Bowel obstruction\n\* History of severe tumour bleeding or bleeding disorders\n\* Poorly controlled anti-coagulation therapy (INR\\>3.0 on coumadin or heparin compounds)\n\* Palliative radiation therapy within 4 weeks prior to registration",  
 "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:  
The provided eligibility criteria \*\*do not mention KRAS mutation status\*\*. Therefore, having a KRAS mutation would \*not\* automatically exclude a patient from this trial. A patient with a KRAS mutation would need to meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria to be eligible.