# 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",  
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 "sex": "ALL",  
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"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 eligibility criteria provided for the clinical trial, there is no specific mention of a KRAS gene mutation being a criterion for exclusion or inclusion. The trial does not specify genetic markers like KRAS mutations as part of the eligibility or exclusion criteria. Therefore, a patient with a KRAS gene mutation would still be eligible as long as they meet the other inclusion criteria and do not meet any of the exclusion criteria listed. However, it's important to note that additional details or context about the trial's specific aims might provide further insight, so it's worthwhile for the patient or their healthcare provider to discuss this directly with the trial coordinators.