# Clinical Trials Data KRAS - Document 32

# Combination Chemotherapy Plus Panitumumab or Bevacizumab for Inoperable Cholangiocarcinoma Without KRAS Mutations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01206049

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically verified adenocarcinoma arisen from gall bladder, extra- or intrahepatic bile ducts or malignant cells consistent with the above and simultaneous radiologic findings consistent with cholangiocarcinoma\n\* Minimum 18 years of age\n\* Curative treatment currently not an option (operation, stereotactic radiation treatment or similar)\n\* KRAS analyzed and found wild-type (wt)\n\* Performance status 0-2\n\* Evaluable disease according to RECIST, i.e. the disease need not be measurable\n\* Hematology: ANC \u22651.5x10\\^9/l. Thrombocytes \u2265 100x10\\^9/l\n\* Biochemistry: Bilirubinemia \u2264 3 x upper normal level. ALAT \u2264 5 x upper normal level.\n\* Creatinine \u2264 upper normal level. At raised creatinine level the measured or calculated GFR must be at least 50% of the lower normal level\n\* Fertile women must present a negative pregnancy test and use secure birth control during and 6 months after treatment. Men with fertile partners must also take care of secure birth control.\n\* Written and orally informed consent\n\nExclusion Criteria:\n\n\* Previous cytostatic treatment of inoperable cholangiocarcinoma\n\* Adjuvant or neoadjuvant chemotherapy, radiation therapy or immunotherapy within 4 weeks prior to treatment start\n\* Other concomitant experimental treatment\n\* Severe medical disease such as considerable heart disease, serious active infection or other disease making the patient unfit for study participation as assessed by investigator\n\* Other malignant disease within 5 years prior to enrolment except from non-melanotic skin cancer and carcinoma in situ cervicis uteri\n\* Interstitial pneumonitis or subsequent pulmonary fibrosis\n\* Pregnant or breastfeeding women\n\* Large-scale surgical intervention, excision biopsy or significant traumatic lesions within 28 days prior to treatment start or presumption that large-scale surgery will become necessary during study treatment.\n\* Significant non-healing wound or ulcers\n\* Active hemorrhage or increased risk of hemorrhage (e.g. tumor invasion in large vessels or known esophagus varices)\n\* Known hypersensitivity to panitumumab, bevacizumab or any of the auxiliary agents\n\* Grade IV fistulas\n\* Uncontrolled hypertension, i.e. symptomatic hypertension or non-medically stabilized hypertension \\>160/100\n\* Haemoptysis \\> 2.5 ml within 2 weeks prior to enrolment\n\* Previous serious and unexpected reactions or know hypersensitivity to two or more of the applied cytostatics",  
 "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:  
No. The inclusion criteria specifically states that the patient must be KRAS wild-type (wt). A patient with a KRAS mutation would be ineligible.