# Clinical Trials Data KRAS - Document 14

# Combined Biological Treatment and Chemotherapy for Patients With Inoperable Cholangiocarcinoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT00779454

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically verified adenocarcinoma arisen from gallbladder, extra or intrahepatic bile ducts or malignant cells consistent with the above and concomitant radiologic findings consistent with cholangiocarcinoma.\n\* Curative treatment presently discounted (surgery, stereotactic radiotherapy, etc.)\n\* KRAS analyzed and found wild-type (wt) or mutated\n\* PS 0-2\n\* Evaluable disease according to RECIST criteria, i.e., the disease does not need to be measurable\n\* Haematology:\n\n \* ANC \u2265 1.5 x 10\\^9/l\n \* Thrombocytes \u2265 100x10\\^9/l\n\* Biochemistry:\n\n \* Bilirubinaemia \u2264 3 x upper normal value\n \* ALAT \u2264 5 x upper normal value\n\* Creatinin \u2264 upper normal value. If raised creatinin, the measured or calculated GFR must be at least 50% of the lower normal value.\n\* Fertile women must present a negative pregnancy test and use birth control during and 3 months after treatment. The following methods are considered safe birth control: Birth control pills, coil, gestagen deposit injection, subdermal implantation, hormonal vagina ring, and transdermal deposit band-aid)\n\* Oral and written informed consent\n\nExclusion Criteria:\n\n\* Chemotherapy within 4 weeks\n\* Radiotherapy within 4 weeks\n\* Immunotherapy within 4 weeks\n\* Other concomitant experimental treatment\n\* Known neuropathy \u2265 grade 2\n\* Serious congruous medical disease\n\* Other previous malignant disease within 5 years, excl. non-melanoma skin cancer and carcinoma in situ cervicis uteri\n\* Previous serious and unexpected reactions to fluoropyrimidine treatment\n\* Hypersensitivity to one or more of the active substances, auxiliary substances or fluoruracil\n\* Patients with interstitial pneumonitis or pulmonary fibrosis",  
 "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:  
Yes, a patient with a KRAS mutation would be eligible for this trial. The inclusion criteria specifically state "KRAS analyzed and found wild-type (wt) \*\*or mutated\*\*". This means the trial accepts patients with either a KRAS mutation or those without (wild-type).