# Clinical Trials Data EGFR - Document 85

# Hepatic Arterial Chemotherapy With Raltitrexed and Oxaliplatin Versus Standard Chemotherapy in Unresectable Liver Metastases From Colorectal Cancer After Conventional Chemotherapy Failure

## Clinical Trial: https://clinicaltrials.gov/study/NCT01348412

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Informed consent signature by the patient-\n\* Cover by an health insurance\n\* Age between 18 and 75 years\n\* Age between 76 et 80 years if patient WHO Status 0\n\* WHO status of 0 or 1\n\* Estimated Life expectancy \\> 3 months\n\* Hepatic metastases of colorectal cancer confirmed on CT Scan without extra-hepatic metastasis (the presence of asymptomatic primary tumor is tolerated)\n\* TEP-Scan without fixation outside the liver and the primary tumor\n\* Histological proven colorectal cancer obtained from primary tumor or the hepatic metastases\n\* Metastases not accessible to curative hepatectomy (impossible R0 surgery or leaving less than 30 % of residual liver), or requiring a complex, very wide hepatectomy (5 segments or more) and\\\\or risky procedure (RPC Class II)- - Presence of hepatic lesion \\> 10 mm on CTScan or hepatic MRI\n\* Failure or arrest of a previous chemotherapy because of intolerance to oxaliplatin, irinotecan, a fluoropyrimidine and/or target therapies (bevacizumab, cetuximab or panitumumab given for tumor expressing wild type Ki-Ras)\n\* Bilirubinemia\\< 1,5 times the superior limit of the normal ( N ),\n\* ASAT and ALAT \\< 5 N,\n\* Creatinemia \\< 1.5 N and creatinine clearance \\> 65ml/mn,\n\* Neutrophils \\> 1,5 x 109/L, platelets 100 x 109/L, hemoglobin \\> 9 g/dL (patients includables even after red blood cell transfusion)-Reference CTScan +/-MRI performed in 21 days preceding the first cycle of treatment\n\nExclusion Criteria:\n\n\* extra-hepatic metastases (presence of 1 to 3 pulmonary nodules, of a maximal diameter of 5 mm with non specific aspect on CTScan and with no fixation on TEP Scan does not constitute a criterion of exclusion)\n\* Symptomatic primary colorectal tumor in place\n\* Contraindication for allergy of rank 3-4 for one of the compounds of chemotherapy- Peripheral neuropathy \\> 2 (Levy Scale)\n\* Current participation or in the 30 days preceding the inclusion in the study in another therapeutic trial with an experimental molecule\n\* Concomitant systemic treatment by immunotherapy, chemotherapy or hormonotherapy- Unbalanced serious illness, unchecked active infection or the other underlying serious disorder susceptible to prevent the patient from receiving the treatment\n\* Pregnancy (pregnancy test compulsory for the inclusion), breast-feeding\n\* Intestinal occlusion or sub-occlusion or history of inflammatory intestinal disease\n\* Other cancer during the 5 years preceding entry in the trial or concomitant (except in situ cancer of the cervix or skin basal cell carcinoma)Patient in custody or under guardianship, Impossibility to adhere to the medical follow-up for geographical, social or psychiatric reason",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided inclusion and exclusion criteria, there is no specific mention of EGFR (Epidermal Growth Factor Receptor) gene mutations as a criterion for either inclusion or exclusion in the clinical trial. The key genetic consideration mentioned is regarding the Ki-Ras (KRAS) gene, where wild-type status is specified in the inclusion criteria related to past treatment with certain targeted therapies.  
  
Since the eligibility criteria do not explicitly disallow patients with an EGFR gene mutation nor do they include EGFR mutations as a specific requirement, the presence of an EGFR mutation would not automatically make a patient ineligible for this clinical trial. However, it is always important to discuss specific patient conditions and genetic profiles with the trial coordinators to ensure eligibility beyond what is explicitly stated in the criteria.