# Clinical Trials Data BRAF - Document 30

# Cetuximab/FOLFIRI With or Without Oxaliplatin and FOLFOXIRI With or Without Bevacizumab in Neoadjuvant Treatment of Non-resectable Colorectal Liver Metastases

## Clinical Trial: https://clinicaltrials.gov/study/NCT01802645

"eligibilityCriteria": "Patients can be enrolled, if all of these conditions apply:\n\n1. Non-resectable, histologically confirmed, synchronous or metachronous colorectal liver metastases.\n2. Non-resectability will be documented by a local multidisciplinary tumour board with participation of a surgeon experienced in liver surgery. Patients can be enrolled if they\n\n a) are technically non-resectable (locally determined by a multi-disciplinary team discussion based on remaining functional liver tissue after resection, i.e. i) involvement of both portal veins, all hepatic veins, portal vein of the liver lobe and hepatic veins draining the segments of the other liver lobe, or ii) other reasons for less than 30% remaining functional liver tissue after resection) and / or b) have \u2265 5 liver metastases and / or c) are regarded as non-resectable for other reasons (description necessary)\n3. Patients with simultaneous liver metastases are eligible,\n\n 1. if the primary tumour was resected at least 1 month prior to chemotherapy or\n 2. all of the following conditions apply:\n\n i) the primary tumour is clearly resectable, ii) no radiation therapy is planned, iii) liver resection is planned before resection of the primary or at the same operation as the resection of the primary, iv) no two-stage liver resection is planned, and v) all efforts were made to exclude additional distant metastases.\n4. WHO PS \u2264 1\n5. Written informed consent\n6. Adequate bone marrow function, liver function (neutrophils \\> 1.5 x 109/l; platelets \\> 100 x 109/l; haemoglobin \\> 5.0 mmol/l (8.0 g/dl); bilirubin \u2264 ULN or \u2264 1.5 x ULN and not increasing more than 25 % within the last 4 weeks; SGOT and SGPT \\< 5 x UNL)\n7. Age \u2265 18 years\n\nExclusion Criteria:\n\n1. Any evidence of extrahepatic metastases, distant lymph node metastases and primary tumour recurrence\n2. (deleted)\n3. Prior systemic anti-tumour therapy with anti- EGFR-, anti-angiogenetic drugs or with chemotherapy (except adjuvant chemotherapy with an interval of \u2265 6 months or in combination with radiation as radio sensitizer)\n4. Radiotherapy or major abdominal or thoracic surgery (excluding diagnostic interventions or venous port implantation) \u2264 4 weeks before study entry\n5. Renal insufficiency with serum creatinine \u2265 1.5 x UNL. If serum creatinine is between 1.0 and 1.5 x UNL, the creatinine clearance according to the Cockroft-Gault formula should be \u2265 60 ml/min\n6. Hypertension with an arterial blood pressure \\> 150/90 mmHg\n7. Severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, unstable angina pectoris, history of myocardial infarction within the last 12 months, significant arrhythmias)\n8. Known proteinuria \\> 1 g/day (to be tested if proteinuria more than 1+ in the urinary dipstick analysis)\n9. Peripheral neuropathy \\> CTC grade I\n10. Concurrent systemic immune therapy, chemotherapy, hormone therapy, or patients receiving immune suppressive treatment (i.e. for transplantation, severe rheumatologic disease)\n11. Participation in clinical trials with investigational agents within 30 days before start of the treatment in study\n12. Active treatment of\n\n 1. peptic ulcers or bleeding erosive esophagitis / gastritis within 3 months before study\n 2. pulmonary embolism, severe or unstable angina pectoris or myocardial infarction, stroke or transient ischemic attack within 12 months before study\n 3. deep vein thrombosis within 4 weeks before study\n13. Inflammatory bowel disease\n14. History of other malignancies, from which the patient is not 5 years disease free, with the exception of colorectal cancer, or adequately treated basal cell or squamous cell carcinoma of skin or in-situ cervical cancer within 5 years before study\n15. History of brain metastases\n16. History of severe psychiatric illness\n17. Active drug- or alcohol abuse\n18. Known hepatitis B or C or HIV infection\n19. Breast- feeding or pregnant women\n20. Lack of effective contraception (for male and female patients)\n21. Known intolerance to one of the following drugs: cetuximab, bevacizumab, oxaliplatin, irinotecan, 5-FU, folinic acid",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

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

Answer:  
This trial is for colorectal liver metastases. The information provided does \*not\* state whether having a BRAF mutation includes or excludes a patient. The eligibility criteria neither mentions BRAF mutations as a requirement nor as an exclusion criterion. Therefore, having a BRAF mutation \*does not automatically disqualify\* a patient, but it also doesn't guarantee eligibility. They would need to meet all other inclusion and exclusion criteria.