# Clinical Trials Data KRAS - Document 29

# Dynamic Circulating Tumor Cell (CTC) Changes During the Chemotherapy in NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01740804

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients with histologically documented, locally advanced or recurrent (stage IIIb and not amenable or combined modality treatment) or metastatic (stage IV) non-small cell lung cancer.\n\* ECOG performance status of \u2264 2.\n\* Patients without prior chemotherapy or therapy with systemic anti-neoplastic therapy. Previous adjuvant or neo-adjuvant treatment or combine chemoradiotherapy for stage I to III is permitted if completed \\> 12 months before enrollment.\n\* According to routine first line doublet chemotherapy in clinical practice, Cisplatin or carboplatin combined with gemcitabine or paclitaxel or docetaxol or Vinorelbine were recommended.\n\* Patients must have measurable disease according to the RECIST (version 1.1) criteria.\n\* Life expectancy of at least 12 weeks.\n\* Age \u2265 18 years.\n\* Written (signed) informed Consent to participate in the study.\n\* Adequate organ function as defined by the following criteria:Liver function: SGOT (AST) and SGPT (ALT) \u2264 2.5 X ULN in the absence of liver metastases or up to 5 X ULN in case of liver metastases. Total bilirubin \u2264 1.5ULN.Bone marrow function: Granulocyte count \u2265 1,500/mm3 and platelet count \u2265100,000/mm3 and hemoglobin \u226590g/dl. Renal function: serum creatinine \u2264 1.5 ULN or creatinine clearance \u2265 60 ml/min. (based on modified Cockcroft-Gault formula).\n\* For all females of childbearing potential a negative serum/urine pregnancy test must be obtained within 48 hours before enrollment. Postmenopausal women must have been amenorrhoeic for at least 12 months to be considered of non-childbearing potential.\n\nExclusion Criteria:\n\n\* Patients with prior chemotherapy or therapy with systemic anti-cancer therapy including target therapy. Previous adjuvant or neo-adjuvant treatment for non-metastatic disease is permitted if completed \u2265 6 months before the enrollments.\n\* Patients with history of any other malignancies within 5 years (except for adequately treated carcinoma in situ of the cervix or basal or squamous cell skin cancer).\n\* Patients who have brain metastasis or spinal cord compression. It is permitted if the patient has been treated with surgery and/or radiation with evidence of stable disease for at least 4 weeks.\n\* Patients who are at risk (in the investigator's opinion) of transmitting human immunodeficiency virus (HIV) through blood or other body fluids.\n\* Nursing or lactating women.\n\* Sexually active males and females (of childbearing potential) unwilling to practice contraception during the study.\n\* Unwilling to write informed consent to participate in the study.\n\* Patients who is unwilling to accept the follow-up.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Advanced NSCLC (stage IIIb/IV or recurrent NSCLC)",

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

Answer:  
The provided eligibility criteria for the clinical trial do not explicitly mention KRAS gene mutations as a factor for eligibility or exclusion. The criteria focus on the stage and status of the non-small cell lung cancer (NSCLC), prior treatments, measurable disease, and general health factors (e.g., organ function, performance status).  
  
Given this information, a patient with a KRAS gene mutation would not be automatically excluded from this clinical trial based on the criteria provided, assuming they meet all other specified inclusion and exclusion criteria. However, it's important to confirm with the clinical trial organizers or the study's principal investigator, as there might be additional considerations or specific genetic studies involved that are not detailed in the brief eligibility criteria.