# Clinical Trials Data EGFR - Document 103

# Nimotuzumab in Combination With Paclitaxel Liposome and Carboplatin (TP Regimen) for the Advanced NSCLC Patients

## Clinical Trial: https://clinicaltrials.gov/study/NCT01393080

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Signature of the informed consent form\n2. Ages from 18 to 70 years old; both male and female.\n3. Pathologically and/or cytologically \u2460 the patients of \u2162B\uff5e\u2163stage NSCLC; \u2461 the patients of IIIA stage NSCLC could not receive the operation or could not operate. \u2462 the patients of IIIA stage NSCLC are recurrent postoperation.\n4. EGFR mRNA from peripheral bloods is positive by ELISA or the expression of EGFR from tumor tissue is positive by immunohistochemical staining.\n5. Functions of major organs( haemogram,heart,liver,kidney)are basically normal, White blood count \u22653.5 x 109/L with neutrophils \u22651.5 x 109/L, platelet count\u2265100 x 109/L, and hemoglobin \u226590g/L.\n\n Total bilirubin \u22641.5 times upper limit of normal (ULN) range; alkaline phosphatase(ALP)\u2264 2.5 times ULN, Transaminases AST (SGOT) and ALT (SGPT) \u2264 2.5 times ULN, serum creatinine \u2264 1.2 times ULN .\n6. With ECOG performance status 0-2;\n7. Both female and male patients must use adequate methods of contraception.\n\nExclusion Criteria:\n\n1. Participation other clinical trials within 1 month prior to inclusion in the trial.\n2. Previous targeted treatment of TKI or EGFR antibodies prior to inclusion in the trial.\n3. Previous paclitaxel liposome and carboplatin (TP) chemotherapy prior to inclusion in the trial.\n4. With other serious internal diseases or uncontrolled infection;refractoriness dysentery or enterospasm, intestinal obstruction.\n5. Cardiovascular diseases history (1)Uncontrollable hypertension, unstable angina, heart infarction, or congestive heart failure and arrhythmia ( happened within 12 month prior to inclusion in the trial) (2)Ischemia checked by ECG, or clinical diagnostic Heart valve disease (3)The patients of Grade II(CTC AE 3.0) of arrhythmia, myocardial ischemia, troponin T abnormality, hypertension or left ventricular ejection fraction \\<50%\uff0ccould not include in the TP+ nimotuzumab test group;\n6. With drug addition, I.e. ,drug-taking, drug-taking for long time; type B hepatitis and C hepatitis in active stage, or with AIDS.\n7. Other malignant tumors, except for skin basal cell carcinoma, or cervical carcinoma in situ, curative carcinoma of prostate.\n8. With history of serious allergic or allergy.\n9. Patients with less compliance\n10. Pregnancy, lactation, fertility but using a prohibited contraceptive method.\n11. Not fit for the clinical trial judged by the investigator.",  
 "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 inclusion and exclusion criteria provided for the clinical trial, a patient with an EGFR gene mutation would be eligible for the trial. The inclusion criteria specifically mention that either EGFR mRNA from peripheral blood needs to be positive by ELISA or the expression of EGFR from tumor tissue must be positive by immunohistochemical staining. This indicates that the trial is indeed targeting patients with positive EGFR expression, which would typically involve EGFR gene mutations.   
  
However, it's important to ensure that the patient also meets all other inclusion criteria and none of the exclusion criteria. Specifically, if the patient has not had previous targeted treatment of TKI or EGFR antibodies, previous paclitaxel liposome and carboplatin (TP) chemotherapy, and doesn't meet any other exclusion conditions, they would be considered eligible for the trial. Additionally, factors such as overall health status (e.g., organ function tests, ECOG performance status) also need to be within the acceptable range as specified in the criteria.