# 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:  
The criteria state that patients must have "EGFR mRNA from peripheral bloods is positive by ELISA or the expression of EGFR from tumor tissue is positive by immunohistochemical staining." This means the trial requires evidence of EGFR expression, \*\*not necessarily an EGFR gene mutation\*\*. While many patients with EGFR mutations will also have EGFR overexpression detectable by these methods, they are not the same thing. A patient could have EGFR overexpression without a specific driving mutation, or could have a mutation with normal expression levels.  
  
Therefore, simply having an EGFR gene mutation does not guarantee eligibility for this trial. The patient would need to meet \*all\* inclusion criteria and \*none\* of the exclusion criteria to be eligible. Specifically, they would need to have positive EGFR expression as measured by one of the specified tests.