# Clinical Trials Data EGFR - Document 40

# Icotinib Following Chemotherapy Versus Chemotherapy as Adjuvant Therapy in Stage IIA-IIIA NSCLC With EGFR Mutation

## Clinical Trial: https://clinicaltrials.gov/study/NCT01996098

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Written informed consent provided.\n\* Aged 18-75 years.\n\* Had completely resected pathological confirmed stage IIA-IIIA NSCLC.\n\* EGFR activating mutation in exon 19 or 21.\n\* Had completed four cycles of platinum-based adjuvant chemotherapy.\n\* Able to start the investigational therapy within 4 weeks after the completion of four cycles of adjuvant chemotherapy.\n\* ECOG performance status of 0-1.\n\* Had a life expectancy of 12 weeks or more.\n\* Adequate hematological function, adequate liver function and renal function.\n\* Able to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\* Female patients, except those who are postmenopausal or surgically sterilized, must have a negative pre-study serum or urine pregnancy test.\n\nExclusion Criteria:\n\n\* Had had previous chemotherapy besides four cycles of adjuvant chemotherapy, radiotherapy, or agents directed at the HER axis (e.g. erlotinib, gefitinib, cetuximab, trastuzumab).\n\* Had a history another malignancy in the last 5 years with the exception of cured basal cell carcinoma of the skin, cured in situ carcinoma of the uterine cervix and cured epithelial carcinoma of the bladder.\n\* Any evidence confirmed tumor recurrence before investigational therapy.\n\* Known severe hypersensitivity to icotinib or any of the excipients of this product.\n\* Evidence of clinically active interstitial lung disease.\n\* Eye inflammation not fully controlled or conditions predisposing the subject to this.\n\* Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous 6 months, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n\* Known human immunodeficiency virus (HIV) infection.\n\* Pregnancy or breast-feeding women.\n\* Ingredients mixed with small cell lung cancer patients.\n\* History of neurologic or psychiatric disorders.",  
 "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 clinical trial eligibility criteria provided, a patient with an EGFR gene mutation would indeed be eligible for the trial, as long as they meet all the inclusion criteria and none of the exclusion criteria. Specifically, the inclusion criteria mention an "EGFR activating mutation in exon 19 or 21," which indicates that the presence of this mutation is a requirement for participation.  
  
Here are some key points to consider for eligibility:  
  
1. \*\*Inclusion Criteria Agreement\*\*:   
 - The patient must have an EGFR activating mutation in exon 19 or 21, which is directly related to your inquiry.  
   
2. \*\*Other Criteria\*\*:  
 - The patient should meet all other inclusion criteria such as age, a completely resected stage IIA-IIIA NSCLC, having completed four cycles of platinum-based adjuvant chemotherapy, ECOG performance status of 0-1, etc.  
   
3. \*\*Avoidance of Exclusion Criteria\*\*:   
 - The patient must not possess any of the exclusion criteria, such as a history of other malignancies within the past 5 years (with specific exceptions), confirmed tumor recurrence, or severe hypersensitivity to icotinib, among others.  
  
If the patient fits these conditions, they would potentially be eligible for participating in this clinical trial. However, it's recommended to consult with the clinical trial coordinators for a detailed assessment of eligibility.