# Clinical Trials Data EGFR - Document 79

# Gefitinib Versus Vinorelbine/Platinum as Adjuvant Treatment in Stage II-IIIA(N1-N2) NSCLC With EGFR Mutation

## Clinical Trial: https://clinicaltrials.gov/study/NCT01405079

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Written informed consent provided.\n\* Males or females aged \u226518 years, \\< 75 years.\n\* Able to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\* Target population is completely resected pathological stage II-IIIA(N1-N2) NSCLC with EGFR exon 19 deletions and exon 21 L858R activating mutation.\n\* Patient who can start the investigational therapy within 3-6 weeks after the complete resection\n\* ECOG performance status 0-1.\n\* Life expectancy \u226512 weeks.\n\* Adequate hematological function: Absolute neutrophil count (ANC) \u22652.0 x 109/L, and Platelet count \u2265100 x 109/L, and Hemoglobin \u22659 g/dL (may be transfused to maintain or exceed this level).\n\* Adequate liver function: Total bilirubin \u2264 1.5 x upper limit of normal (ULN), Aspartate aminotransferase (AST), alanine aminotransferase (ALT) \u2264 2.5 x ULN in subjects without liver metastases; \u2264 5 x ULN in subjects with liver metastases.\n\* Adequate renal function: Serum creatinine \u2264 1.25 x ULN, or \u2265 60 ml/min.\n\* Female subjects should not be pregnant or breast-feeding.\n\nExclusion Criteria:\n\n\* Known severe hypersensitivity to gefitinib or any of the excipients of this product.\n\* Known severe hypersensitivity to pre-medications required for treatment with cisplatin / vinorelbine doublet chemotherapy.\n\* Inability to comply with protocol or study procedures.\n\* A serious concomitant systemic disorder that, in the opinion of the investigator, would compromise the patient's ability to complete the study.\n\* A serious cardiac condition, such as myocardial infarction within 6 months, angina, or heart disease.\n\* Interstitial pneumonia.\n\* Patients with prior exposure to agents directed at the HER axis (e.g. erlotinib, gefitinib, cetuximab, trastuzumab).\n\* Patients with prior chemotherapy or therapy with systemic anti-tumour therapy (e.g. monoclonal antibody therapy).\n\* Patients with prior radiotherapy\n\* History of another malignancy in the last 5 years with the exception of the following:Other malignancies cured by surgery alone and having a continuous disease-free interval of 5 years are permitted. Cured basal cell carcinoma of the skin and cured in situ carcinoma of the uterine cervix are permitted.\n\* Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n\* Eye inflammation or eye infection not fully treated or conditions predisposing the subject to this.\n\* Evidence of any other disease, neurological or metabolic dysfunction, physical examination or laboratory finding giving reasonable suspicion of a disease or condition that contraindicated the use of an investigational drug or puts the subject at high risk for treatment-related complications.\n\* Patient who has active serious infection (e.g. pyrexia of or 38.0\u2103 over)\n\* Patients who harbouring exon 20 T790M mutation.",  
 "healthyVolunteers": false,  
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"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 provided eligibility criteria from the clinical trial, a patient with an EGFR gene mutation may be eligible if:  
  
1. They have a completely resected pathological stage II-IIIA(N1-N2) NSCLC with EGFR exon 19 deletions or exon 21 L858R activating mutation.  
2. They do not harbor the exon 20 T790M mutation, which is explicitly listed as an exclusion criterion.  
  
If the patient meets the inclusion criteria regarding the EGFR mutations and does not have the exon 20 T790M mutation, among meeting other criteria, they may be eligible for the trial.