# 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,  
 "sex": "ALL",  
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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:  
A patient with \*just any\* EGFR gene mutation would \*not\* automatically be eligible for this trial. The inclusion criteria specifically require the presence of \*EGFR exon 19 deletions\* or \*exon 21 L858R activating mutations\*. Other EGFR mutations, including the T790M mutation (which is specifically excluded), would disqualify the patient.  
  
So, to be eligible, the patient must:  
  
1. \*\*Have either an EGFR exon 19 deletion OR an exon 21 L858R mutation.\*\* Other EGFR mutations are not eligible.  
2. \*\*Meet all other inclusion criteria:\*\* age, stage of NSCLC, timing of surgery, performance status, life expectancy, organ function, etc.  
3. \*\*Not have any of the exclusion criteria:\*\* prior therapies, other health conditions, etc.